

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF SOUTH DAKOTA (SOUTHERN DIVISION)

3 * * * * *

4 UNITED STATES OF AMERICA, et al,
Plaintiff,

5 vs.

6 ASFORA, et al,

7 Defendants.

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* CR No.

* 4:16-cv-04115-LLP

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* MOTIONS HEARING

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* JULY 23, 2020

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9 TRANSCRIPT OF MOTIONS HEARING

10 BEFORE THE HONORABLE LAWRENCE L. PIERSOL,

11 U.S. DISTRICT COURT JUDGE

12 ALL APPEARANCES OF PARTICIPANTS IN THIS HEARING WERE

13 REMOTELY BY VIDEOCONFERENCE OR TELEPHONIC CONFERENCE

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1 PROCEEDINGS ~ July 23, 2000

2 Before Hon. LAWRENCE L. PIERSOL, Judge

3

4 (All appearances at this proceeding are via
5 videoconference or telephonic conference.)

6 (Proceedings in open court at 12:16 p.m.)

7 THE COURT: Good afternoon. This is Judge
8 Piersol. I'm going to go through appearances to begin
9 with.

10 First of all, who's appearing for the Plaintiff
11 United States of America? And by the way, as you appear,
12 if you can't hear me the way I'm speaking now, tell me.
13 Okay? So who's appearing for the United States of
14 America?

15 MS. ROCHE: Good afternoon, Your Honor. This is
16 Megan Roche appearing on behalf of the United States, and
17 I can hear you fine.

18 THE COURT: Good. All right.

19 MS. BAILEY: Good afternoon, Your Honor. This
20 is Ellie Bailey appearing on behalf of the United States.
21 And I can also hear you fine.

22 MS. SONG: Good afternoon, Your Honor. This
23 is --

24 THE COURT: Hold on. Hold on. Wait a minute.
25 All right. Ms. Bailey. Then next, who's

1 appearing?

2 MS. SONG: This is Harin Song, also on behalf of
3 the United States. And I'm appearing by telephone. And I
4 can hear you well. Thank you.

5 THE COURT: All right. Yes. All right. Thank
6 you.

7 Then for the Plaintiff Dustin Bechtold?

8 MR. ANDERSON: Robert B. Anderson at May, Adam,
9 Gerdes and Thompson in Pierre, appearing for both
10 plaintiffs Bechtold and Wellman, Your Honor. I can hear
11 you fine.

12 THE COURT: All right. Good.

13 Are you Jay Holland?

14 MR. HOLLAND: Good afternoon, Your Honor. Yes.
15 Jay Holland also appearing for Dr. Wellman and Bechtold.

16 THE COURT: There is also Veronica Nannis here?

17 MS. NANNIS: Yes, Your Honor. Good afternoon.
18 Veronica Nannis also on behalf of Doctors Wellman and
19 Bechtold. Thank you.

20 THE COURT: And then for the Defendant Wilson
21 Asfora?

22 MR. GEYERMAN: Good afternoon, Your Honor.
23 Grant Geyerman from Williams and Connolly on behalf of all
24 defendants.

25 THE COURT: All right. Is Benjamin Graham also

1 on the phone?

2 MR. GRAHAM: Yes, Your Honor. I'm here. I can
3 hear you just fine.

4 THE COURT: All right. Then the local counsel,
5 Steve Landon?

6 MR. LANDON: Yes, Your Honor. Steve Landon and
7 Brett Lovrien are here as well.

8 THE COURT: And then I understand that
9 Mr. Landon and Mr. Lovrien, you're in one office. And a
10 part of yours, Alex Hagen, is in another office. Is that
11 right?

12 MR. LANDON: That's correct.

13 MR. HAGEN: Yes, Your Honor. Alex Hagen.

14 THE COURT: I'm not seeing you, Alex.

15 MR. HAGEN: I'm sorry, Your Honor. I'm not
16 seeing anyone on mine. I can't see the video. I've lost
17 the video. But I don't have a speaking role, so I'm
18 content to just listen. I don't know what the issue is.

19 THE COURT: All right. All right.

20 THE CLERK: Mr. Landon, you're giving feedback.
21 Would you mute your mic when you're not speaking, please?

22 THE COURT: All right. It's the defendant's
23 motion, so the defendant will lead off. And identify
24 yourselves again before you speak.

25 MR. GEYERMAN: Thank you, Your Honor. This is

1 Grant Geyerman. Myself, along with my co-counsel, have
2 the pleasure of representing Dr. Wilson Asfora and his two
3 wholly owned medical device companies.

4 Approximately 30 years ago Dr. Asfora came to
5 Sioux Falls after receiving his educational medical
6 training in his native Brazil and from institutions such
7 as Oxford and Brazil. He's nationally recognized and
8 likely is the most accomplished neurosurgeon ever to
9 practice in Sioux Falls, if not the entire state.

10 Unfortunately, this misguided lawsuit, filed originally by
11 two younger surgeons who competed for patients with
12 Dr. Asfora and now joined by the Department of Justice
13 that intervened as a principal party in interest, has
14 tarnished that reputation in the final years of his
15 career.

16 All three defendants, Dr. Asfora and his two
17 wholly owned medical device companies, have moved to
18 dismiss the complaint in its entirety. In the complaint
19 the government is asserting violations of the Federal
20 False Claims Act under one of two distinct theories of
21 liability. One theory is premised on the supposed taking
22 and receiving of kickbacks, and the other is predicated on
23 Dr. Asfora having performed unnecessary surgeries on
24 federal healthcare beneficiaries.

25 And while the complaints -- the government's

1 complaints and its brief at times blurs the line between
2 these two theories, in doing so it obscures the clear
3 legal and pleading deficiencies with each theory. They
4 are, in fact, separate theories, and we're going to talk
5 about them today separately.

6 As to each theory, the defendants have three
7 separate and independent grounds upon which that claim can
8 be dismissed and should be dismissed. The first and
9 predominant theory in the complaint, what we've called the
10 ownership kickback theory, is not actually where I'd like
11 to start the presentation today. Given that you're most
12 interested in the medical necessity theory, that's where I
13 would plan to start. My colleague, Mr. Graham, will
14 handle our presentation on the ownership kickback theory,
15 if that's acceptable to Your Honor for us to split the
16 argument.

17 The False Claims Act, which is the principal
18 cause of action that's asserted in this case, has three
19 prima facie elements: One, false or fraudulent claim for
20 payment. Two, that the defendant acted knowingly; the
21 mens rea component to the statute. And third, that the
22 falsity was material to the government's decision to pay.

23 This is an Anti-Fraud Statute. It's not in
24 statute intended to police compliance with regulatory
25 regimes or to substitute for a medical malpractice action.

1 It's a fraud statute. And because it's an Anti-Fraud
2 Statute, the heightened pleading requirements of Rule 9(b)
3 apply in addition to the normal requirements of Rule
4 12(b) (6), and we have arguments that are predicated on
5 each of those rules independently.

6 So to start, Your Honor, we sent a couple of
7 hours before the hearing here some slides to your
8 chambers. We sent them to opposing counsel as well. I
9 don't know if you got a copy of them or not. There are
10 just a few of them. But I may reference those slides
11 during our presentation just to orient us all where we're
12 at.

13 And in -- I'll start with slide three, which is
14 a slide that lists both the ownership kickback theory and
15 the separate and independent arguments that we have for
16 dismissal of those claims, and separates the bases for
17 dismissal of the medical necessity theory claims. And as
18 they say, I want to start with the medical necessity --

19 THE COURT: Oops. I just lost you.

20 MR. GRAHAM: I think I hit space bar and muted.

21 THE COURT: Now you're back.

22 MR. GEYERMAN: Okay. Thank you. As to the
23 medical necessity theory, we have three independent
24 grounds for dismissal: One, the complaint has not
25 sufficiently alleged repetitive surgeries to support a

1 false claim on a medical necessity theory; meaning, a
2 surgery that the allegations demonstrate was medically
3 unnecessary for a federal beneficiary for which a claim
4 for payment was submitted to the government.

5 Number two, that the complaint's allegations do
6 not demonstrate that Dr. Asfora's surgeries qualify as
7 medically unnecessary under the law.

8 And three, that the complaint contains
9 insufficient allegations to demonstrate scienter, as
10 needed under the False Claims Act, meaning that Dr. Asfora
11 knew or recklessly disregarded the possibility that his
12 surgeries were medically unnecessary.

13 Each of those grounds is independent of one
14 another. And if one of the three is granted, all claims
15 associated with the medical necessity theory would be
16 dismissed.

17 Now, before I get into more detail, I would note
18 at the outset that the principle under which the first and
19 the third of those arguments are based is not a real
20 principle that the government seeks. Rather the
21 battleground in this case is whether the complaint's
22 allegations moot that principle.

23 As to the second argument, we do have a
24 disagreement about what the government's legal rule is.
25 Because as I understand the government's position, they're

1 saying that per se a trial court cannot dismiss on a
2 motion to dismiss claims because the allegations are
3 insufficient to demonstrating lack of medical necessity.

4 We disagree with that, based in part on these
5 four cases cited in our brief where other trial courts
6 have dismissed claims for inadequate allegations of a lack
7 of medical necessity of the motion to dismiss. But we are
8 in agreement on the governing legal principle for two of
9 these arguments, and we dispute it at the third. So let
10 me just say that at the outset.

11 Moving to discussion, then, of the first legal
12 ground, that there are not sufficient representative
13 examples of a claim that could be false under this theory,
14 within the Eighth Circuit it is well established precedent
15 that the government later has to prove, quote, "some
16 representative examples," end quote, of the violation of a
17 False Claims Act, unless the plaintiff has personal
18 knowledge of the false claim or otherwise the allegations
19 bear sufficient indicia of reliability.

20 This principle indicates back to the *Joshi* case
21 from the Eighth Circuit from 2006 and was reaffirmed as
22 recently as last year in the *Strubbe v. Crawford County*
23 *Memorial Hospital* case. And the principle is that this is
24 a fraud statute, and under line B you have to plead fraud
25 with particularity. And as a manifestation of that in the

1 Eighth Circuit, you need to prove some representative
2 examples of a false claim.

3 The government's position here is not that every
4 surgery that Mr. Asfora performed was medically
5 unnecessary, nor that the government and the two relaters
6 were in the surgeries when they were performed so they
7 don't have personal knowledge of this. Therefore, they
8 are required to follow the representative sample rule that
9 is a requirement in the Eighth Circuit. And so you need
10 to, when scrutinizing the public's allegations, look for
11 three things, three requirements:

12 One, was the surgery of a federal beneficiary?

13 Two, were there claims for payments put in to
14 the government for that surgery?

15 And three, are they adequately alleging that the
16 surgery was medically unnecessary?

17 If the surgery doesn't check all three of those
18 boxes, it's inadequate to demonstrate a sample violation
19 of the False Claims Act under a medical necessity theory.

20 And so, to try to respond to where I think
21 perhaps, Your Honor, might find this argument of most
22 assistance, we prepared slide four of our set of slides,
23 which is a table that lays out the 21 different patients
24 for whom a surgery is referenced in the complaint.
25 They're listed in complaint number order.

1 And we have in the three red columns to our
2 table, is there an allegation that they're a federal
3 beneficiary, is there an allegation of a claim for
4 payment, and what if anything is said on the issue of
5 medical necessity.

6 And so early in this complaint, the first 260
7 pages -- sorry, paragraphs, that is -- there's lots of
8 references to difference surgeries that were performed on
9 federal beneficiaries for whom claims for payment were
10 submitted to the government. But not -- for not one of
11 those surgeries is there any suggestion that the surgery
12 was inappropriate or much less that it was not medically
13 necessary.

14 But then there's a pivot in the complaint to a
15 section that tries to leave the impression that there were
16 some surgeries that were performed that were not medically
17 necessary. And there's really only four surgeries that
18 are alleged where there's any discussion at all about was
19 this a good surgery or not, and that's rows 18 through 21
20 of our table. And for three of those four, they're not
21 even federal beneficiaries, and there's no reference to a
22 claim for payment. For all we know they had private
23 insurance and the government had no role in that surgery
24 at all. Only for patient Bonnie, who's on line --

25 MS. BAILEY: Your Honor, if I could object? I

1 would object to Mr. Geyerman using any patient names, as
2 protected health information and in violation of HIPAA,
3 and in particular 45CFR164.514, which does not allow names
4 of patients to be identified. So to the extent that
5 Mr. Geyerman plans to read patient names in open court,
6 the government would object.

7 THE COURT: How can she be identified, then?

8 MS. BAILEY: Well, this individual could be
9 identified if you can connect the individual's name to the
10 complaint, to the date.

11 South Dakota is a small community. Sioux Falls
12 is a small community. It's not that difficult to connect
13 the dots. So I think it's inappropriate to utilize names.
14 And we would prefer that -- excuse me.

15 THE COURT: Surgeries in Sioux Falls, though,
16 come from a fairly wide area. We're a major medical
17 center. We're the major one between Denver, and Omaha,
18 and the Mayo Clinic in Rochester, Minnesota. So we draw
19 from a big area. So I don't know that it's that likely,
20 if that's your argument.

21 MS. BAILEY: Our preference, Your Honor, is that
22 we utilize paragraph numbers from the complaint, and the
23 objection is noted. But I understand your position.

24 THE COURT: All right. Go ahead.

25 MR. GEYERMAN: Your Honor, I intentionally only

1 used a first name to try to avoid precisely that issue,
2 names in the complaint. So I will proceed cautiously.
3 But I wanted -- I want us to be able to know that we're
4 talking about the same surgery, so that's why I put a name
5 on it.

6 So we're talking about that one patient's
7 surgery, and she's the only individual for whom she's a
8 federal beneficiary, claim for payment to the government,
9 and there's any suggestion that the surgery is in
10 question.

11 Under the *Frazier* case out of the District of
12 Arizona that we cited in our brief, every other surgery
13 referenced in the complaint is irrelevant to their
14 assertion that there was a violation of a False Claims Act
15 because he was performing medically unnecessary surgeries.
16 They don't check all the boxes. Those other surgeries
17 don't matter at all.

18 So let's talk about the four patients, then,
19 whose surgeries the complaint does allege some level of
20 criticism about them. And if you flip in our slides to
21 the next page, slide five, that's a table that drills down
22 in a little more detail about the four surgeries; again,
23 three of whom aren't even federal healthcare
24 beneficiaries.

25 But what's obvious from the table is that we're

1 talking about four surgeries that all involve fusing of
2 multiple levels of the spine. And this is four surgeries
3 out of approximately 4,800 during the period of the
4 alleged conspiracy that this person performed, that
5 Dr. Asfora performed. Now that number is not in the
6 complaint; I will admit that. The government didn't
7 provide any denominator that you can assess how
8 frequently --

9 THE COURT: Where does the 4,800 come from?

10 MR. GEYERMAN: Your Honor, it comes from
11 counsel's investigation of the facts. And I believe that
12 number has been shared --

13 THE COURT: Well, wait a minute. This is a
14 motion to dismiss. This isn't a motion for summary
15 judgment.

16 MR. GEYERMAN: Understood. And I guess -- the
17 only point I can make from the complaint, Your Honor, is
18 the government doesn't identify any denominator from which
19 Your Honor could draw a conclusion about how prevalent in
20 terms of how many total surgeries Dr. Asfora performed
21 these four represent.

22 And so the allegation about them is that they
23 were aggressive, or quite aggressive; that the surgery
24 might have been more conservative, or that many surgeons
25 would not have performed this surgery. But what the

1 allegations do not say is that -- they don't say that any
2 of these surgeries were medically unnecessary. They're
3 more equivocal, softer conclusions than that. And
4 frankly, as is evident, this is a debate over how many
5 levels of a spine fusion was appropriate. Was three
6 appropriate, or was four? Was four appropriate, or was
7 five? We are debating a matter of degree in terms of what
8 was the best surgery.

9 But for purposes of false claims liability, the
10 question is not what is the best surgery that should have
11 been performed, but rather was it medically unnecessary.
12 And I'd submit that when you look at the medical necessity
13 cases where a complaint is found to have plausibly
14 alleging a lack of medical necessity, they're not
15 disputing issues that are a matter of degree, but rather
16 there was no medical value at all to the surgery or to the
17 test or to the prescription drug that was at issue.

18 And so one would draw a distinction analytically
19 between the criticisms that are a matter of degree, where
20 there's no suggestions the surgery shouldn't have been
21 performed at all, it's rather how many levels of the
22 spinal fusion were appropriate.

23 And to try to bring this home for Your Honor, if
24 you flip to the next slide, we tried to get as specific as
25 we could about what it is about the nature of these

1 criticisms of his spinal surgeries, his four surgeries
2 that --

3 THE COURT: Aside from the individual surgeries,
4 what about the fact that the use by Dr. Asfora, according
5 to the allegations, that his use of the bullet cage
6 increased exponentially as time went on?

7 MR. GEYERMAN: Several responses. Number one,
8 that is really talking about the other theory of liability
9 that the government is asserting; that he was engaging in
10 kickback schemes and he profited from his sale of the
11 bullet cage. I -- it's notable on these four surgeries
12 that are alleged to have been medically unnecessary, they
13 don't tell you how many implants were used in those
14 surgeries, nor do they allege under the surgery he should
15 have performed that he would have implanted any fewer
16 implants.

17 Which is to say -- that's a demonstration that
18 there's really no analytical nexus between the complaints
19 they're making about he shouldn't have been operating a
20 medical device company that manufactured devices he used
21 himself. That's one theory. And we're going to talk
22 about why they fail to state a claim under the kickback
23 arrangement.

24 But completely independent of that is their
25 assertion in performing medically unnecessary surgeries.

1 In other words, let's take the patient whose name will go
2 unspoken where a four-level fusion was performed on her.
3 The complaint does say that an Aegis screw was used in
4 that surgery. It doesn't say how many screws were used.
5 And it also says the complaint is she -- you could have
6 performed that surgery with fewer levels of fusion.

7 Okay. But there's no suggestion that if you'd
8 done three levels of fusion instead of four you would have
9 used fewer Aegis screws. We don't even know how many
10 screws got used in the first place.

11 Our position is that whether something was
12 medically unnecessary analytically is entirely separate
13 and distinct from the question about what implants were
14 used. Because they're making a completely different
15 theory of liability on implants, which is a kickback
16 theory of liability. They're saying it was necessarily
17 tainted because he had an ownership interest in the
18 company supplying devices.

19 And it's only because, quite frankly, the
20 Anti-Kickback Statute is trying to prevent doctors from
21 overprescribing or performing unnecessary procedures that
22 caused them to enact the kickback statute in the first
23 place.

24 But there's no actual nexus here between the
25 surgeries that are alleged to have been unnecessary and

1 his use of more implants than would otherwise had been
2 used had it been the appropriate surgery.

3 So we view these as separate and distinct legal
4 theories. We think it's important that Your Honor look at
5 them as separate and distinct legal theories. And we
6 think that it's -- as a pleading and tactical matter,
7 honestly. It's really where the government has decided to
8 try to blur the lines between those two theories that the
9 complaint sort of gets confusing. Medical necessity
10 should have nothing to do with whether he owned or didn't
11 own Medical Designs. He either performed unnecessary
12 procedures, or he didn't. It doesn't matter what the
13 implants were that were a part of that procedure.

14 So, rooting this in sort of the case law that
15 exists with respect to other cases where lack of medical
16 necessity has been asserted, here's where the complaint in
17 this case falls short:

18 Number one -- this is on slide six where we
19 tried to put citations into other cases and hide them with
20 specific insufficiencies with this one. Number one,
21 there's no definitive allegation of an absence of medical
22 justification for these four surgeries. Remember, three
23 of them don't even matter because they're not even federal
24 beneficiaries. But there's no opinions saying no
25 reasonable surgeon would have performed this surgery. And

1 again, the standard to have liability for a lack of
2 medical necessity is that there is no medical
3 justification. So you need something akin to no
4 reasonable surgeon would have done "X."

5 This dispute is a matter of degree. And so
6 really, the foundations in this case are more like the
7 *McFarland* case out of the Middle District of Florida where
8 there the allegation was that the defendant had prescribed
9 certain medications that were not allegedly medically
10 necessary.

11 And when you scrutinize the complaint, the
12 allegations were that it was highly unlikely that the
13 medication would have some appurtatious benefit for the
14 patient, or it was doubtful that the patient would benefit
15 clinically from the medication. And the Court said that
16 doesn't rise to the level of showing an absence of medical
17 necessity even if it's questionable, highly questionable,
18 whether there would be some effectiveness.

19 Second, the complaint cites no objective
20 standards underlying the criticisms that are lodged
21 against Dr. Asfora's surgeries. And that really hits home
22 when you look at the case the government showcases in its
23 brief, the *Polukoff* case out of the Tenth Circuit. There
24 it was a doctor who was performing a certain heart
25 surgery. And there was an American Heart Association, an

1 American Stroke Association guideline that said you do not
2 perform this surgery for any purpose other than to cure,
3 essentially, recurring strokes.

4 But the allegation in that case was that that
5 doctor believed that that procedure actually helped cure
6 migraines. But because insurance didn't cover the surgery
7 when done to treat migraines, he would misrepresent the
8 purpose for which he was performing the procedure.

9 And the reason the allegations plausibly alleged
10 a lack of medical necessity is because there was an AMA,
11 or an American Heart Association, an American Stroke
12 Association guideline. That guideline had been
13 specifically adopted by the treating hospital as the
14 operative internal guideline. And their allegation was
15 that, quote, general agreement in the medical community
16 was that that procedure should not be performed for any
17 purpose other than to prevent recurring strokes.

18 That's the kind of concrete, identifiable
19 standard that should exist if you're going to allege that
20 performing a procedure is not medically necessary.
21 Because if you don't have some sort of third-party
22 objective standard against which to measure whether this
23 surgery was or wasn't appropriate, you're really running
24 into the realm of second-guessing clinical judgments. And
25 the Supreme Court has said that the federal False Claims

1 Act is not meant to be a statute to punish medical
2 malpractice. It's not meant to be a replacement for the
3 state code that regulates doctors.

4 This is a fraud statute. And so reasonable
5 differences of medical judgment don't rise to the level of
6 demonstrating a lack of medical necessity. And so the
7 absence of any objective standard that's alleged in the
8 complaint to show why these surgeries at four levels
9 instead of three were medically unnecessary is a legally
10 significant omission.

11 Number three, the complaint wasn't identified,
12 the details about who the individuals are that rendered
13 these critiques of these surgeries. We're not given
14 names. We're not given full credentials. And it doesn't
15 even -- the complaint doesn't even --

16 THE COURT: Wait a minute. Wait a minute. That
17 seems to be stretching it a bit. As one of the details
18 you have to have in a complaint, you give the name.
19 That's obviously discoverable, as are the credentials.
20 But to suggest that in the complaint you have to not only
21 name the person that you're quoting, but beyond that that
22 you have to have their credentials, even under a 9(b)
23 standard, which this is, I think that's one that can be
24 required.

25 MR. GEYERMAN: I'm not trying to set a bright

1 line rule, Your Honor. Ultimately the standard is have
2 they specifically pled details under the Eighth Circuit's
3 representative sample requirement to sufficiently prove to
4 Your Honor this is a claim that if proven true would be a
5 violation of the statute.

6 And in the absence of a third-party, an
7 objective standard, in the absence of -- in the
8 circumstance here, again, it's a matter of degree. It's
9 not he should never have performed any surgery on these
10 four people at all; it's that he should have just fused
11 fewer levels of the spine instead of the number of levels
12 that he did.

13 Our submission is from a holistic consideration
14 of how good are these allegations? Do they warn of chinks
15 going forward into discovery against this defendant? We
16 submit that the fact that we don't even know who these
17 reviewers are is significant. And one reason we don't
18 know is we don't even know their name.

19 THE COURT: Well, you do -- you'll know them
20 pretty soon if the case goes forward.

21 MR. GEYERMAN: Well, I'll only know them if they
22 tell me or if I ask. You're right.

23 And the fourth point I would add is that in some
24 cases when a complaint has been found to not plausibly
25 allege medical necessity, the plaintiff went as far as to

1 even attach the underlying report of the surgery or the
2 procedure so that when a court is evaluating on a (9) (d)
3 analysis, are there specific details here: Is there
4 enough to have this case survive the pleading stage? I
5 can at least look at the full medical record and report.

6 The complaint here doesn't do that. Rather --

7 THE COURT: It was suggestion --

8 MR. GEYERMAN: -- we only have --

9 THE COURT: -- can't hear what the -- just a
10 minute.

11 You're suggesting a standard with an attachment
12 of medical reports and so on to a complaint, that even on
13 a 9(b) I think is beyond the requirements of a 9(b), just
14 so you know --

15 MR. GEYERMAN: Well, again --

16 THE COURT: -- to be discovered.

17 MR. GEYERMAN: I'm not advocating or suggesting
18 that a bright line removal be created. But again, from a
19 holistic evaluation of this complaint, are the allegations
20 sufficiently specific? The fact that they have shared and
21 served certain quotations -- not even complete sentences,
22 I might add, not even a block quoting. This is the
23 entirety of the conclusions section. They've not quoted
24 it.

25 And we obviously know more about these

1 procedures than are in the complaint, and if -- we have a
2 lot to say about this. But I'm limiting it to this point
3 as to what's in the complaint, and it's not very much, and
4 they're not even attaching the whole medical record.

5 So that's our second basis for dismissal of the
6 medical necessity claims, is that there aren't sufficient
7 allegations to demonstrate these -- this one procedure is
8 in fact medically unnecessary.

9 And with the third and final ground for
10 dismissal of the medical necessity claim is that there are
11 no allegations in this complaint that Dr. Asfora himself
12 actually believed these procedures were medically
13 unnecessary. And that is a fatal omission to this
14 complaint. Because the knowing submission of false claims
15 is a prima facie element of a cause of action. And so not
16 only does the surgery had to have been medically
17 unnecessary --

18 THE COURT: Just a minute. Just a minute.
19 Let's touch that a little bit. Because there's a claim by
20 the defense that says risk assessment, so to speak, is
21 going to 95 percent. That goes to the top five percent of
22 the risk element. And so -- that he put in his medical
23 notes, I didn't think this was necessary surgery, he
24 obviously isn't going to do that.

25 So the -- it could be said that the government

1 gets the opportunity to try and show to a jury that, in
2 fact, he didn't or loosely have significant wording that
3 he was going to -- the situation wasn't medically
4 necessary since the score level is so high.

5 And what kind of evidence do you extract for
6 ability to show intent? Intent is usually shown by
7 circumstantial evidence.

8 MR. GEYERMAN: It is typically shown by
9 circumstantial evidence. But they don't have any -- they
10 don't allege any circumstances about him in these
11 surgeries at all.

12 As to the risk score point, that -- there's very
13 little that's alleged in the complaint about what that
14 risk score means. They call it a risk score, but they
15 don't actually allege very much about that Vanderbilt
16 University scaling score. What they do allege is that it
17 measures patient satisfaction. That's the only concrete
18 fact that is alleged in the complaint about what that
19 measures. And it says that he has a high risk score on
20 a -- on something that leads to customer satisfaction.

21 So in terms of -- I don't think a fair inference
22 can be drawn between him having a high score on that and
23 the fact that he had some reason to believe that a
24 particular surgery was medically unnecessary. They're
25 certainly drawing no connection between the four surgeries

1 they complain about and that risk score. There's nothing
2 direct to the complaint to that fact. And I would say
3 that we've cited cases where the Court, in dismissing at
4 the motion to dismiss stage a medical necessity claim,
5 makes note of the fact that there are no allegations that
6 suggest the defendant believed the surgery was
7 unnecessary.

8 It's a prima facie element. And we're not
9 asking you to obviously judge any evidence in this case,
10 but we are asking that the plausibility of their
11 allegations be scrutinized. And even giving them the
12 benefit of all inferences for what they've alleged, we
13 believe that they haven't plausibly alleged any facts on
14 misuse of scienter, because they don't say anything about
15 him and these particular surgeries.

16 I guess I would just note that the government in
17 its brief argues that it's essentially impossible for a
18 defendant to prevail on the argument that allegations in a
19 complaint don't demonstrate medical necessity at the
20 motion to dismiss stage. And we cited *McFarland*, *Plavix*,
21 the *Health Management Associates* case infringer that all
22 did the exact opposite. And the conclusion there is not
23 the procedures were medically necessary, but rather the
24 complaint's allegations are not sufficiently plausible and
25 specific to suggest that they're not medically necessary.

1 That's the specific procedural test before Your Honor, and
2 we don't think that they've done it.

3 That -- those are our three points for grounds
4 for dismissal of the medical necessity claim. This is not
5 any -- this is not a medical malpractice statute; it's an
6 Anti-Fraud Statute. And we don't believe that they've met
7 their pleading burden.

8 Unless Your Honor has more questions on that
9 theory, I would turn it over to Mr. Graham to talk about
10 the ownership kickback theory, if Your Honor would like.

11 THE COURT: All right. No, I don't have any
12 further questions.

13 I was obviously concerned about medical
14 necessity. That's one of the reasons I keyed it up for
15 people to argue. I'm not so concerned about the owner
16 kickbacks, so we'll see how your partner does on that.

17 MR. GRAHAM: Thank you, Your Honor. This is Ben
18 Graham from Williams and Connolly. I'll be addressing the
19 second theory that is raised in the complaint, which we
20 have described as the ownership kickback theory.

21 Now, I'd like to be clear at the outset about
22 what the government's theory of the case is here. On the
23 government's view as expressed in the complaint and the
24 opposition brief, any time a doctor wholly owns a medical
25 device company, uses a device from that company in one of

1 his surgeries, and then receives his ordinary profit
2 distribution from that company, the government believes
3 that doctor has committed a crime in violation of the
4 Anti-Kickback Statute.

5 That is a novel and sweeping theory of
6 liability, and it should be dismissed for any one of three
7 reasons that you identified, both in the slides we handed
8 up this morning and also the briefs from this case.

9 The first reason applies generally as a matter
10 of law. There is no kickback. The complaint fails to
11 even -- does not allege and pursue a cognizable theory as
12 a general matter under the Anti-Kickback Statute. That's
13 true in this case and in every other.

14 The second theory is more particular to the
15 allegations about Dr. Asfora and Medical Designs in
16 particular. And the second ground is that as applied to
17 Dr. Asfora and his company, the complaint does not
18 adequately allege scienter. The AKS, as you know, is a --

19 (Static and sound distortion.)

20 (Reporter asked for clarification.)

21 MR. GRAHAM: The second ground, Your Honor, is
22 scienter; that under the AKS, that's a heightened mens rea
23 burden, and the government must allege that Dr. Asfora and
24 his companies knowingly and willfully engaged in the
25 unlawful conduct.

1 And the third ground is that the complaint for
2 similar reasons does not allege materiality, which is a
3 necessary element under the False Claims Act.

4 Now, I'd like to go through those in order, and
5 I'll try to do so briefly.

6 So the first is the very nature of this
7 ownership kickback theory. Now under the Anti-Kickback
8 Statute, it criminalizes behavior where two actors
9 exchange financial incentives to encourage the other actor
10 to shift government beneficiaries towards the first's
11 services or medical -- medical services.

12 Now, the government here in this case is
13 pursuing a novel theory: That a doctor who wholly owns a
14 medical device company kicks back to himself by receiving
15 profit distributions. To our knowledge and based on
16 everything that the government has attempted to put in in
17 the opposition, no court has ever held that that was a
18 viable theory. No agency guidance from HHS has ever
19 reached so far. And indeed, based on the government's
20 complaints that are reached for as attachments to its
21 opposition, it doesn't even appear that the government
22 itself has ever brought a case on that theory, targeting a
23 doctor who wholly owns a medical device company. And
24 that's for good reason.

25 The AKS focuses on inducement, as the efforts of

1 one actor through financial incentives to change the
2 behavior of another. The cases we cited to Your Honor say
3 that's the gravamen of Medicare fraud. Here, the AKS
4 violation is inducement.

5 And I think the clearest case to explain this
6 standard and the structure that we care about when looking
7 at kickbacks is probably the *Patzer* case, from the Eastern
8 District of Wisconsin. We cite that on page 14 of the
9 brief. And I'll just quot a couple of sentences from it,
10 because I think it encapsulates the core of our defense
11 and it's one to which the government has not offered a
12 response.

13 "The very definition of kickback requires that a
14 person provide something of value; one, to another person;
15 and two, to improperly obtain or reward favorable
16 treatment."

17 Now those two elements are the very elements
18 that are lacking here. There are not distinct people, and
19 nothing was offered to induce or to change the behavior of
20 the other.

21 The Court in *Pastor* continues to say, "Implicit
22 in this definition is the idea that each party of the
23 kickback transaction is acting independently and can
24 choose or could have chosen not to deal with the other.
25 If such independence is lacking, then one party who is

1 providing something of value for another could not be
2 viewed as incentive."

3 THE COURT: Let me ask you a question.

4 MR. GRAHAM: Yes.

5 THE COURT: According to the allegations, again,
6 Dr. Asfora approached other physicians in saying if you
7 use my bullet, then I'll kickback, frankly, "X" number of
8 dollars for every one that you used. And according to the
9 allegations again, they said I can't do that, that's
10 illegal.

11 But how is that different than if you consider
12 his corporation to be a separate entity, how is it any
13 different than when Dr. Asfora winds up getting, in
14 essence, a sum of money separate and apart from the
15 surgery that he performed, for doing it? How's that any
16 different from what he offered to do with some other
17 surgeon who turned him down?

18 MR. GRAHAM: Your Honor, two responses to that.
19 The first is that the alleged payment and his consulting
20 fees to other physicians and other surgeons, those aren't
21 part of this case, because those are investigated and
22 settled and released as part of the DuBay investigation,
23 (indiscernible) 2011 to 2013.

24 Now as to the hypothetical Asfora approaches
25 another doctor and offers to pay them --

1 THE COURT: We've got an audio problem a little
2 bit. You're getting scrambled. Let's do a testing. One,
3 two, three, four.

4 MR. GRAHAM: One, two, three, four.

5 THE COURT: That was clear. So I think maybe --
6 Misty? Maybe a little more slowly. You weren't speaking
7 that fast, but it was getting a little bit garbled here.
8 So go ahead. Not that what you're saying is garbled at
9 all, but the way it was coming was garbled, okay.

10 MR. GRAHAM: I'll ask my computer to be a better
11 messenger.

12 So the difference is, Your Honor, I think is on
13 a couple of fronts. One of those is that in that context,
14 there is a different actor. And in that allegation,
15 Dr. Asfora alleged to be offering remuneration to a third
16 party for purposes of directing patients towards devices
17 from his company.

18 In the context of Dr. Asfora and his company
19 directly, you have to look at the verbs in the statute.
20 There is no "offer." There is no "inducement." There
21 isn't a "solicitation." Dr. Asfora does not need to
22 solicit his profit distribution from his company. His
23 company does not offer the profit distribution to
24 Dr. Asfora. Those terms don't even apply in the context
25 of a wholly owned medical device company; which sets this

1 apart from all of the other cases the government would
2 like to discuss about the doctor-owned distributorships.

3 And I think those cases are instructive on this
4 point. Because if you look at the HHS guidance and the
5 special fraud alerts, what they say is that a company that
6 is owned by a physician is not unlawful, but it should be
7 subject to scrutiny.

8 THE COURT: Well, one of the companies was owned
9 by the physician and his wife. The other one was owned by
10 him solely. Isn't that the case?

11 MR. GRAHAM: That's right, Your Honor.

12 THE COURT: What about this one that was with
13 the physician and his wife? Even if you take your theory
14 that he can't solicit himself, what about the fact that
15 there's a third party involved with regard to at least the
16 conspiracy claim?

17 MR. GRAHAM: So in this context, and under the
18 statute, a physician and his wife are treated as one in
19 the same purposes, one in the same person. The government
20 disregards the distinction between them for the ownership
21 interest. The so that's why I refer to them as wholly
22 owned.

23 In our opening brief we cited statutory
24 authority for that, which I can flip back to in a moment
25 and probably forward you in response. So there is for

1 this only one owner, and that is the married entity, and
2 it disregards payments to a spouse.

3 So in both Medical Designs and in Sicage, for
4 purposes of this statute and for the healthcare laws,
5 there is one owner in both.

6 And that sole ownership is a distinguishing
7 factor in this case from the others in which the
8 government has pursued claims against entities that have
9 physician owners.

10 Now, in those cases, Your Honor, I would
11 actually just direct you to the ones the government cites
12 in their brief. If you read those cases, in each of them
13 the entity that was at issue, the pod or physician-owned
14 distributor, was generally a new entity that was created;
15 It was one that solicited investments from multiple
16 different doctors explicitly for the purpose of demanding
17 that they make referrals through that entity, and then
18 siphoning money back through it to disguise cash payments.
19 And the hallmarks of fraud are all over those entities.

20 For example, in the *Iqbal* case from the Eighth
21 Circuit, someone approached for a business relationship --
22 the defendant approached another entity for a business
23 relationship where he would direct referrals to that
24 company and demanded a share of the proceed in return.
25 And to get that off the ground, they created, quote, bogus

1 consulting agreements.

2 In the *Bruno v Schaeffer* case, also in the
3 government's brief, positions were offered for investments
4 in laboratory entities, but, quote, existed in name only
5 and didn't physically exist and were not licensed labs.

6 By contrast to all of those cases, there is a
7 sole owner who is a real doctor, who created real
8 companies for the purpose of making real products.
9 Medical Designs was founded in the nineties, so that
10 Dr. Asfora could create his bullet cage, patent that
11 product, get FDA approval for it, and then use it in his
12 operations. That's a far cry from the abusive fraud
13 tactics that are at issue in the other cases the
14 government cites.

15 And still, in none of those cases has the
16 government sought to bring a charge against a sole owner
17 of a medical device company. That's why this theory in
18 this case is novel and would sweep far too broadly and,
19 frankly, wreak havoc across the entirety of the medical
20 industry. And it has bad policy outcomes, too.

21 We want expert physicians like Dr. Asfora, who
22 is one of the best and most renowned physicians practicing
23 in the Midwest, to be able to develop products for use in
24 these complex surgeries.

25 Your Honor, I'd also like to touch briefly on

1 the second two grounds for why this ownership kickback
2 theory would have to be dismissed in relation to
3 Dr. Asfora in particular. As I said, the AKS is a
4 criminal statute. Under Eighth Circuit law there's a
5 heightened mens rea burden. And under the *Jayne* case what
6 it means is the government has to show that conduct was,
7 quote, obviously evil, or that Dr. Asfora intended to
8 engage in unlawful conduct.

9 Now, as Your Honor pointed out, mens rea can be
10 established through circumstantial evidence, but there are
11 precisely no allegations in the complaint that Dr. Asfora
12 believed that this was unlawful conduct. There are
13 allegations about what other people said, to be sure. And
14 it's also the case that other companies and other
15 hospitals didn't want to do business with physician-owned
16 entities because they were concerned about precisely this
17 situation. The government has been very aggressive in
18 pushing these theories. There are trouble indicatives
19 under the FCA, and there's good reason why someone in
20 business might want to avoid this as a prophylactic
21 matter. But that doesn't mean that it's unlawful. And in
22 fact, Dr. Asfora had very good reason to believe that his
23 ownership structure was lawful.

24 The DuBay investigation revealed that he was the
25 owner of Medical Designs, that he was using Medical

1 Designs for products in his surgeries, and that he was
2 receiving profit distributions from Medical Designs.

3 The government received that information in a
4 complaint from a relater. HSS, the Office of Inspector
5 General, the very agency responsible for paying Medicare
6 claims, issued subpoenas and investigated the matter and
7 reached resolution. And they did not pursue a claim that
8 the ownership structure was a violation of the AKS.

9 So in contrast to every other actor who might
10 tread lightly in this area that might be concerned about
11 government overreach, Dr. Asfora had already been through
12 this investigation, and the government had not made a
13 claim on the basis of his ownership structure.

14 That is the same ownership structure under the
15 entirety of the ownership kickback theory. They believe
16 that the mere fact of ownership, use of the product, and
17 receipt of product distributions violates the AKS. When
18 Dr. Asfora had very good reason that that was not the
19 case, because all let it passed on the very claim.

20 Now the --

21 THE COURT: Just a minute. Just a minute.

22 Now you're saying that because of the DuBay
23 case, that Dr. Asfora has reason to believe that what he
24 was doing was fine? Is that what you're saying?

25 MR. GRAHAM: Yes. Yes, Your Honor, we are.

1 THE COURT: So why did he pay \$650,000 in
2 settlement?

3 MR. GRAHAM: Over a different allegation than
4 DuBay, Your Honor. The one allegation was that Dr. Asfora
5 was paying cash payments through the closing agreements to
6 other doctors. That was one of the allegations in DuBay.
7 DuBay overrid the allegation that Dr. Asfora himself was
8 using these products and receiving a product fee. Those
9 are in the complaint. Those are the kinds of information
10 that were sought by the subpoena. And then the actual
11 settlement agreement did not raise as misconduct the
12 receipt of profit distributions. The settlement only
13 focused on the cash payments to other doctors.

14 And as we discussed earlier in the hypothetical
15 that Your Honor raised, payments to other parties, to
16 third parties, is the kind of thing that creates AKS
17 liability. And in the settlement Dr. Asfora of course
18 admitted -- (sound distorted) -- but the prevailing part
19 is that the government did not pursue a claim in that case
20 that the ownership and profit distribution was also an AKS
21 violation.

22 So after being sent through the wringer with the
23 government and sitting through subpoenas and with
24 negotiating the settlement with the government, Dr. Asfora
25 had good reason to believe that the ownership part --

1 THE COURT: Wait a minute. Wait a minute.

2 The settlement wasn't actually with the
3 government, because the government declined to undertake
4 the case. And so the other parties received it. And
5 under the (sound garbled) proceedings, the government has
6 to give notice of it in case they're going to intercede in
7 order to object to the settlement. So the settlement
8 wasn't with the government. Right?

9 MR. GRAHAM: Two points, Your Honor. The
10 government -- in false claims cases has right of approval
11 for settlement agreements and can intervene at any time.
12 The government did decline to intervene. But the
13 government also played an active role in that case when it
14 issued the subpoenas and received information about Dr.
15 Asfora's ownership.

16 THE COURT: Right. But the Anti-Kickback Act
17 requires that they receive the information during the
18 proceedings. But when you look at the pleadings in the
19 case, there wasn't anything in the pleadings. No
20 discovery was reflected. There's not even an answer
21 reflected.

22 MR. GRAHAM: Well, Your Honor, the discovery
23 happens before the complaint is unsealed. So when the
24 complaint is filed or (indiscernible) files it under seal,
25 the government gets the notice and the government issues

1 subpoenas, conducts a thorough investigation, and then
2 will make a decision whether or not to intervene before
3 the case --

4 THE COURT: Yes, I'm familiar with that.

5 MR. GRAHAM: As you may know from this case, if
6 not from others, the government was involved in that
7 investigation. The subpoenas that we attached to our
8 motion to dismiss, Your Honor, I believe it's ECF number
9 74-2, is a subpoena issued by HHS which they --

10 THE COURT: What do you have to say then about
11 even the warnings that he got from his own lawyers that he
12 shouldn't -- you can't do this? What about that?

13 MR. GRAHAM: Well, Your Honor, the lawyers, as
14 you know, are notoriously risk averse. And Dr. Asfora's
15 counsel advised him that there were risks associated with
16 some of the transactions he was contemplating agreeing to
17 with these other third parties and the licensing
18 arrangements. But they also said that it would expose
19 Dr. Asfora potentially to a qui tam action, could expose
20 him potentially to an action by the government, but that
21 there would be defenses. Dr. Asfora's counsel never told
22 him that this was illegal or unlawful. They did counsel's
23 job and advised him of the risks.

24 And that advice ended up being correct in that
25 respect. The government has pursued a claim, and it has

1 led to the result of Dr. Asfora suffering tremendous
2 economic harm. That doesn't change the fact that under
3 the scienter standard, materiality standard, or the basic
4 nature of an ownership kickback, there is no liability
5 under the AKS, despite the government pursuit of it.

6 And, Your Honor, speaking to the government's
7 role in the DuBay investigation as well, that underpins
8 the third reason for dismissing the ownership kickback
9 theory. And I think it's under the False Claims Act
10 there's a materiality requirement. And under the Supreme
11 Court's reasoned decision in *Escobar*, that is a rigorous
12 standard and it's one that should be enforced on a motion
13 to dismiss.

14 And here's the issue: Under *Escobar*, if the
15 government is aware of what it perceives to be predicate
16 facts that would indicate that there was an HHS violation,
17 and it does nothing for years and continues unabated to
18 pay the claims that Dr. Asfora submits under that same
19 very ownership structure that the government was on notice
20 of, then under the Supreme Court's holding in *Escobar*,
21 that is strong evidence that there is no materiality.

22 In other words, if the government is correct on
23 the first hand that there is this broad, sweeping
24 liability under the ownership kickback theory -- which we
25 contest but they seem to believe there is -- they knew

1 every predicate element --

2 THE COURT: (Static and garbled sound.)

3 MR. GRAHAM: I'm sorry, Your Honor?

4 THE COURT: Strong evidence. Not that this
5 evidence is strong and this is enough to kick out the
6 claim and so on. Strong evidence doesn't sound like
7 something that a court should be considering in its ruling
8 on the 12(b) (6) motion as opposed to a summary judgment
9 motion.

10 MR. GRAHAM: Your Honor, courts do dismiss FCA
11 claims on the grounds of materiality on the pleadings.
12 And we're not asking Your Honor to balance the evidence.
13 But the government does have a burden under Rule 8(a) and
14 12(b) (6) to name plausible inference of a materiality
15 theory, and the Supreme Court emphasizes that this is a
16 rigorous standard.

17 It's the kind of bait and switch that *Escobar*
18 was trying to prevent. The government knew that
19 Dr. Asfora owned this company and was using these devices.
20 It was front-page news for years. And they allowed him to
21 continue making a claim for payment and paying them. HHS,
22 the same entity that investigated the allegations in
23 DuBay, continued to make those payments . And what the
24 government is not allowed to do under the *Escobar* standard
25 is to lead an doctor down the garden path and then years

1 later turn around and sue for liability. It's unfair, and
2 it is dismissible under the *Escobar* standard.

3 So, Your Honor, for any of these three reasons,
4 because the ownership kickback theory at large does not
5 constitute a kickback, because there was no plausible
6 allegation of scienter, even when investigated before, and
7 because the government continued to pay without raising
8 the issue for nearly a decade, each of which is an
9 independent reason that we think the ownership kickback
10 theory should be dismissed. Thank you.

11 THE COURT: Thank you. I'll hear from the
12 government.

13 MR. GEYERMAN: Your Honor, before the government
14 starts -- I would just add there are several sort of
15 secondary claims brought for conspiracy, payment by
16 mistake, and unjust enrichment. We're happy to rest on
17 the papers on that, unless Your Honor has questions.

18 And because Your Honor asked specifically about
19 the settlement agreement from the DuBay case, I direct you
20 to docket number 743. The settlement agreement from DuBay
21 is in the record on the motion to dismiss, and the
22 government is a signatory to that settlement agreement.
23 And a Sanford hospital paid one hundred percent of the
24 settlement payment. There was no payment by Dr. Asfora.

25 THE COURT: Except that I have the settlement

1 agreement right here with me, And there's nothing in the
2 record that says that Sanford paid a hundred percent.

3 MR. GEYERMAN: That part is true; that is not in
4 the record. But I am representing that that is true.

5 THE COURT: I don't question your
6 representation. I just point that out, you know. Because
7 this is kind of an unusual 12(b) (6) hearing because we're
8 talking about a lot of things, some of which aren't in the
9 record. That's why I make the point. I don't question
10 your representation; on the other hand, I don't accept it
11 as being a part of the record before me.

12 All right. With regard to the other claims, the
13 unjust enrichment and the other things, the duplicate
14 recovery and all that, you've briefed all that, so I don't
15 have any questions with regard to those.

16 I pointed counsel specifically to the things I
17 was especially concerned about, which you've covered well
18 in your briefs as well as here. And the other things have
19 been covered adequately already. Well, as to those two
20 issues too. But I'm obviously interested in hearing on
21 the two issues I specified not only from you, but likewise
22 from the government, because those are ones that you've
23 put forward forcefully in your briefing.

24 All right thank you, then.

25 Let me hear from the United States.

1 MS. ROCHE: Thank you, Your Honor. This is
2 Megan Roche, speaking again after you requested that we
3 identify ourselves. Can you hear me okay, Your Honor?

4 THE COURT: Yes. Go ahead.

5 MS. ROCHE: Thank you. And may it please the
6 Court, counsel.

7 The United States respectfully requests that the
8 Court deny defendant's motion to dismiss United States'
9 complaint in intervention.

10 THE COURT: Just a moment. I've lost my
11 realtime.

12 (Off the record to resolve technical issues.)

13 MS. ROCHE: As I was saying, the United States
14 respectfully requests that the court deny defendant's
15 motion to dismiss.

16 The United States' complaint in intervention,
17 the United States has met the necessary standard in
18 Federal Rule of Civil Procedure 12(b) (6) and then has
19 stated sufficient factual matter. It's well pleaded and
20 accepted as true that the stated claim for relief is
21 plausible on its face.

22 The United States has acknowledged, just as
23 defendants have already stated, that 9(b) is, of course,
24 at issue in this case as we are discussing matters under
25 the False Claims Act. And so the United States does have

1 to state with particularity the circumstances constituting
2 fraud. The defendant has already established there are
3 essentially the two theories of the case: The medical
4 necessity claims, and the Anti-Kickback Statute
5 violations. As the Court has suggested it's more
6 interested in the medical necessity claims, there's where
7 I will begin and attempt to respond to the arguments
8 that --

9 THE COURT: Let me ask you -- just a moment.

10 On the medical necessity claim, in this
11 complaint there's less detail with regard to specific
12 cases than there was originally. Isn't that correct?

13 MS. ROCHE: You mean by originally the
14 difference between relaters' complaint and the United
15 States' complaint?

16 THE COURT: Yes.

17 MS. ROCHE: Yes, that's a fair -- as far as
18 discussing specific procedures and attacking medical
19 judgment and medical choices and procedures, that's a fair
20 assessment. There was a number of discussions of specific
21 provision violators in the complaint.

22 THE COURT: Hum. They told us -- (sound
23 garbled).

24 MS. ROCHE: What's that?

25 THE COURT: That was the reason for calling

1 some -- for removing some of the detail, culling some of
2 the detail.

3 MS. ROCHE: Right, Your Honor. And I'll get to
4 that, as to what I think that the United States' pleading
5 requirement is under 9(b) as to what needs to be pleaded
6 for 9(b) to be satisfied for the medical necessity claim.

7 And so just a quick snapshot and some background
8 information, considering we've talked about what
9 constitutes medical necessity as defendants began arguing.
10 And of course Medicare and Medicaid only cover services
11 and items that are reasonable and necessary for the
12 diagnosis or treatment of illness or injury.

13 Of course as the parties already have briefed
14 that if there's a nonreimbursable claim that's submitted
15 to federal healthcare programs, that claim is false. And
16 if a claim is not medically necessary, that is also false.
17 I don't think there's any disagreement about that.

18 But the defendants have already discussed sort
19 of this degree of difference between medical judgment and
20 that information. I'll get into that a little bit further
21 here. But we did want to discuss in the *Polukoff* case, a
22 Tenth Circuit case, that case -- and we cited it in our
23 briefs -- specifically said that to be reasonable and
24 necessary a procedure must be among other things
25 appropriate, and that includes the duration and the

1 frequency, and furnished in accordance with accepted
2 standards of medical practice. And then finally, meets
3 but does not exceed patient's medical need.

4 And that's just one case, *Polukoff*, and it's
5 cited in the brief. And that's something to just keep in
6 mind as I guess into the next argument about what the
7 standard is in the Eighth Circuit as to what the United
8 States has to show under 9(b) at this stage of the
9 litigation regarding the medical necessity claim.

10 So the defendants have asserted at this stage
11 that it's imperative that the representative sample, the
12 representative or example patient be pleaded at this
13 point. And we would actually disagree with that at this
14 stage and based on the law in the Eighth Circuit. Of
15 course the parties talked about *Joshi* a fair amount, and
16 in the pleadings and also here in argument today, but the
17 Eighth Circuit has a different test. And it was briefly
18 mentioned, but I don't think it was highlighted enough.
19 And that's discussed in the *Thayer* case, the *Thayer versus*
20 *Planned Parenthood*. And that was cited in our opposition
21 brief. And in *Thayer*, the Court there noticed -- it's a
22 Judge Wollmann opinion -- a party can satisfy Rule 9(b)
23 without pleading representative examples of false claims
24 if the party can otherwise plead that the particular
25 details of a scheme to submit false claims paired with

1 reliable indicia that lead to a strong inference that
2 claims were actually submitted.

3 And so that was a case, *Thayer*, that essentially
4 said *Joshi* always saying there must be a representative
5 patient example is not the law. And *Thayer* was a little
6 bit different in the fact that there was a pretty wide
7 Circuit sweep and a Circuit analysis. And I think that
8 *Thayer* discussed or cited at least seven but probably
9 eight other sister Circuits that also talked about the
10 reliable indicia test under *Thayer*.

11 And so in examining that is sort of where
12 defendants have said that the lines get blurred. And in
13 this instance we do believe that in some respects the
14 lines should get blurred. Because if you're talking about
15 all of the specific and the particular details that are in
16 the United States' complaint, it covers the majority of
17 all the paragraphs in that complaint, a lot of which is
18 talking about the ownership interest, the ownership
19 theory, the alleged kickbacks, the structure and
20 arrangement of the types of distributions that Medical
21 Designs was engaged in, that Sicage was engaged in, that
22 Dr. Asfora was engaged in.

23 And so to talk about the particular details of
24 the scheme for the whole -- the entirety of the United
25 States' claim, we have to talk about all of the things

1 that were alleged and what schemes were alleged.

2 The schemes that were alleged are more
3 specifically talking about what was Medical Designs doing,
4 what was Dr. Asfora doing, what was Sicage doing, how are
5 the arrangements starting? Talking about the bullet cage.
6 Although the bullet cage was FDA cleared long ago, it was
7 substantially equivalent to other things.

8 And so like Your Honor has suggested earlier
9 with questions, at that time Medical Designs was not
10 finding very many users for the bullet cage. And so
11 Dr. Asfora, as an owner and also as an agent, approached a
12 number and a varied amount of other people, including his
13 coworkers at Sanford, and also including just a random
14 surgeon, a random neurosurgeon in the Dakota Dunes and
15 expressly said I will give you "X" amount of money simply
16 for you using this device.

17 And so that was alleged with particularity, and
18 there was sufficient details of that whole theory of the
19 case just talking about the bullet cage, in talking about
20 Medical Designs, in talking about how money flowed
21 between -- if Dr. Asfora is going to order a product that
22 Medical Designs manufactures, like the bullet cage, he
23 says I have a surgery on this date and I need "X" amount
24 of screws, I need "X" amount of cages, and submits for --
25 you know, basically submits to Medical Designs this is

1 what I need, and those -- you know, the Medical Designs
2 then bills Medicare for all of those devices, and
3 eventually throughout the process distributes those
4 proceeds back to Dr. Asfora. That's exactly the sort of
5 harm and concern and the corruption of medical judgment
6 that the Anti-Kickback Statute is intending to reach.

7 And so it's not just that; it's all of the
8 schemes. It's about the bullet cage. It's about the
9 SAMBA screw. It's about Sicage and how Sicage was created
10 essentially to be a replacement billing source for
11 Dr. Asfora, because he could no longer distribute -- or
12 Medical Designs could no longer distribute the SAMBA screw
13 because it was sold to Orthofix.

14 And so it really is sort of -- if we're talking
15 about all of the schemes that the government has alleged,
16 it has to be the entirety of the complaint and not just
17 the medical necessity claims, which we'll get to.

18 And I can talk about, you know, the -- a lot of
19 the really concerning evidence in those schemes. Not just
20 those was kickbacks that we already discussed, where
21 Dr. Asfora offered physicians money to use Medical
22 Designs' products. But other things: A lot of secretive
23 and furtive behavior as far as what Dr. Asfora told
24 Sanford, what Dr. Asfora told CMS, what Dr. Asfora told --
25 through various forms and things like that.

1 But also Orthofix is a very big and important
2 scheme that's discussed with extensive paragraphs in the
3 complaint. And part of the reason that Orthofix is so
4 concerning, Your Honor, is because Dr. Asfora, in that
5 instance, had innovated, and he had brought something to
6 market that other users besides himself were using -- the
7 SAMBA screw -- to the point where it was sold to another
8 distributor who wanted to distribute that product. And
9 there was a lot of back and forth during the negotiation
10 that's discussed in the complaint in detail and with
11 particularity, and discusses throughout that whole process
12 that Dr. Asfora's continuing to negotiate on behalf of
13 Medical Designs, back and forth, back and forth. He
14 wanted to be able to make money when he, himself,
15 Dr. Asfora the physician, used the SAMBA screw at Sanford,
16 at the Sioux Falls Specialty Hospital, and other places.
17 And Orthofix had to come back repeatedly and say you can't
18 get royalties off of your own use of the device. You
19 don't want to violate the anti-kickback laws.

20 And there was this tension of continually going
21 back and forth, continually going back and forth. And
22 eventually there was a transfer in who could distribute
23 the SAMBA screw, and Orthofix became the licensee or the
24 distributor of that device. And still Dr. Asfora is
25 constantly asking, I want Medical Designs to get it back,

1 just for my practice. I want to get it back, just for my
2 practice. And to the point where he's saying again and
3 again, I'm motivated to market my SI practice. I'm
4 motivated to do more surgeries. And that's going on back
5 and forth. And he's getting all these warnings for
6 Orthofix.

7 And so all of these -- all of these allegations
8 are viewed together about what's in Dr. Asfora's mind,
9 what's happening between the business decisions of Medical
10 Designs and Sicage with Dr. Asfora as an owner or agent,
11 versus Dr. Asfora as the surgeon.

12 And so we've got the bullet cage instances.
13 We've got the Orthofix instances, where eventually even
14 though Medical Designs was not the distributor of SAMBA
15 screw, Medical Designs continued anyway to distribute the
16 SAMBA screw when Dr. Asfora was utilizing the SAMBA screw
17 in a procedure and didn't tell Orthofix about that.

18 And thus he con -- Medical Designs continued to
19 attempt to make money; and thus Dr. Asfora, in the
20 process, continued to make money on a device that he had
21 already sold.

22 And additionally with the Sicage, that's another
23 variation, I suppose, on the kickback and ownership theory
24 as it's discussed. Because Sicage was another example
25 where it's an SI screw substantially equivalent to the

1 SAMBA screw that was sold to Orthofix, and Sicage was
2 essentially a Dr. Asfora and Medical Designs, essentially
3 Medical Designs as a distributor, can no longer catch the
4 proceeds from utilizing an SI screw it developed, Medical
5 Designs and Dr. Asfora developed, a substantially
6 equivalent product.

7 And so then Medical Designs, which became
8 Sicage, which is another sort of thing, Sicage was created
9 as a separate LLC but it has a nearly identical address,
10 the same employees, Dr. Asfora as the sole owner. But
11 it's a separate entity. We'll admit that.

12 But that entity was created essentially, we
13 believe the evidence shows and we've alleged and we've
14 pled with particularity that for the purpose of
15 Dr. Asfora and Medical Designs wanting to be able to
16 capture the proceeds from his use of an SI screw at
17 Sanford.

18 And so that sort of furtive and behavior of
19 creating a new entity, depending on what was happening
20 with the Orthofix agreement about the SAMBA screw, but
21 this new entity and creating it to allow Sicage to
22 distribute this SI screw for Dr. Asfora's use at Sanford.

23 So there's a lot of these sort of -- all these
24 things are swirling together and I don't think can be set
25 aside, especially when *Thayer* tells us what are the

1 particular details of the scheme? And that scheme
2 includes the kickback theories, and that scheme includes
3 the medical necessity claim.

4 But the second part, not just of the particular
5 details of the scheme in *Thayer*, is we're talking about
6 the reliable indicia. And so reliable indicia, in at
7 least one case that's already been discussed today here
8 where a court has decided what has constituted reliable
9 indicia is that *Polukoff* case out of the Tenth Circuit.
10 In there the Tenth Circuit found that the relater, who is
11 the relater not the government in that case, had stated a
12 claim where among other things that surgeon had allegedly
13 performed an unusually large number of procedures; that
14 other physicians had object the to the surgeon's practice;
15 and procedures violated industry and hospital guidelines,
16 which was discussed to some degree earlier here today.

17 And the government would suggest that the
18 reading of the complaint at the pleadings stage, the
19 reliable indicia that you have to look at and you have to
20 consider is exactly that PARS data that Your Honor has
21 already raised where as alleged in the complaint Sanford
22 is giving Dr. Asfora essentially his risk score for the
23 years of 2008 to 2014. And as we noted in the complaint,
24 that risk score increased each year. I think during that
25 period it doubled, various times, as we allege in the

1 complaint.

2 Eventually, in that last reporting year in 2014,
3 Dr. Asfora was in the top .5 percent of all physicians,
4 and I think was the 12th neurosurgeon among all
5 neurosurgeons in the United States. And that's for his
6 specialty. Neurosurgery is a high-end surgery. It's
7 risky. You're in brains. You're in backs.

8 And so that's particularly relevant, I think in
9 this case, when we're talking about the statistics or
10 items like that, that the *Polukoff* court may have
11 considered.

12 The physician complaints are particularly
13 important in this case. Your Honor has already addressed
14 that the relaters themselves -- one is a neurosurgeon; one
15 is an orthopedic surgeon -- but both had overlapping
16 practices with Dr. Asfora. And we can assume, I think, at
17 this stage and based on all of the allegations in the
18 complaint, there was a sharing of patients. And I think
19 it was noted in the complaint that Dr. Bechtold is a
20 specialist in hip procedures, and the hip is very close to
21 the SI joint for the SAMBA screw that Sicage. And of
22 course Dr. Roman, the other relater, is a partner or was a
23 partner, neurosurgeon doing a lot of the same spine work.

24 But to be honest about the complaints that are
25 specifically alleged in our complaints, the United States,

1 the controlling complaint, there was a Sanford
2 physician -- and we've talked about that in the complaint
3 at paragraph 133 -- that specifically said and was
4 concerned that Dr. Asfora owns the company that makes the
5 bullet cage, he has an income from his use of the cage.
6 After the cage was FDA cleared he was using the cage also
7 exclusively. He's doing a large number of multiple-level
8 spinal fusions. And specifically this physician used the
9 word "outlier."

10 And so that was particularly relevant and very
11 specific, very detailed, talking about the owners with
12 interest that we've already discussed, talking about the
13 potential harm to patients as far as solely using just one
14 device in which he has an ownership interest and receives
15 money, doing a large number of multiple-level spinal
16 fusions, which as you'll see in a lot of the external and
17 internal peer reviews alleged in the complaint are called
18 extremely rare in various circumstances. And we'll also
19 see in those peer reviews that many are noted to be very
20 dangerous to the patient, depending on the patient's
21 characteristics.

22 And I'll get into those in the peer reviews.
23 There were some internal peer reviews that we noted in the
24 complaint. And there was one case in that instance, it
25 was a five-level fusion; internally the committee that

1 reviewed it, there was eight Sanford surgeons that
2 reviewed that case, and that was a specific instance where
3 five bullet cages were used. Obviously we know Dr. --
4 Medical Designs and Dr. Asfora had an interest in bullet
5 cages. That committee found that that procedure was
6 aggressive in the situation -- that's at complaint
7 paragraph 272. It varied from the standard of care. It
8 was a lengthy procedure, meaning it may have been more
9 expansive than necessary than what the patient's need was.

10 THE COURT: That's a -- just a moment. Just a
11 moment. "Varied from the standard of care," well, that's
12 the sort of thing that you hear in medical malpractice
13 cases. But how much does that help you where we've got a
14 fraud case?

15 MS. ROCHE: No, I think that's right, Your
16 Honor. And we don't disagree that the standard is not
17 whether somebody was negligent. I think the reason that
18 we're using a lot of these -- a lot of these peer reviews,
19 especially, is because they're independent at this point,
20 and it's not the government's expert telling everyone that
21 this is a medically unnecessary procedure. These are
22 independent parties. And if we're talking about something
23 to the effect of the degree to -- which we touched upon
24 earlier, the *Polukoff* case did say that whether or not a
25 specific procedure or -- is reasonable and necessary, you

1 can consider the appropriateness of the procedure, the
2 duration and the frequency. Also, one that itemizes that
3 the procedure be one that meets but that does not exceed
4 the patient's medical need.

5 And so I think especially when you're dealing
6 with the spine and levels, it is sort of a unique
7 situation in comparison to stents or things like that,
8 just because there are so many levels. And it's just a
9 sort a different animal.

10 But we think all of this information is
11 certainly relevant and is something that should be
12 considered when we're talking about reliable indicia, when
13 we're talking about schemes, when we know that Dr. Asfora
14 has that ownership interest. And so a lot of these peer
15 reviewers are saying why is there no documentation about
16 why these two extra levels were done? Well, why -- why is
17 this physician so aggressive? Or this sort of case would
18 go to review in my hospital for analysis of what was done
19 here.

20 And it's really to understand exactly what the
21 government's concern here is that Dr. Asfora was motivated
22 by greed and was motivated by making money. And at this
23 stage the degree matters, I think, in the spine.
24 Especially in some of these cases where the reviewers
25 found that there was harm as a result of a procedure being

1 too long or being too aggressive. Because I think in one
2 instance, at least, there was paraparesis; and I think
3 that's the case that we're talking about presently, the
4 internal purity case, the five-level fusion, and patient
5 harm. And I think there was also the discussion of
6 increase in surgical time. That can have dramatic harm on
7 patients. The but that's just one of the examples. And
8 that's with eight physicians reviewing it and coming to a
9 consensus.

10 The external peer reviews we find are even more
11 stark and even more helpful. Because -- you know, the
12 common lay person may not know how often an internal
13 purity process may happen. But an external purity
14 process, you know, for the most part at this point, it's
15 either eventually the government's expert that's talking
16 about medical necessity, but here it's independent
17 physicians with no stake in the outcome in this matter,
18 and they're not being paid -- well, they're being paid,
19 but not for the specific purpose of a litigation.

20 And there's this sort of distinction between
21 whether or not the government can rely on these other
22 cases if there's not a medical beneficiary. But again, we
23 think it goes back to the way in which that we had to
24 plead with particularity the scheme itself. And the
25 scheme itself definitely involves how many devices

1 Dr. Asfora was using in a procedure, you know, for those
2 20 patient examples that was listed in the chart here, the
3 defendants put up. We still think that those are
4 relevant, especially understanding the ownership
5 interests.

6 It's important for the Court to know, and it's
7 relevant under the scheme as indicia how much money are we
8 talking about here. Because in the response brief
9 defendants routinely say things like Dr. Asfora wouldn't
10 do something for a couple hundred dollars or, you know,
11 thousands of dollars, or whatever. But there's some very
12 high dollar amounts in those instances, and there's a lot
13 of overlap between the products that Dr. Asfora has an
14 ownership interest. So in a lot of cases there's SAMBA
15 screws, there's bullet cages, there's Aegis screws,
16 there's a surgical plate onto other devices that Medical
17 Designs distributes. And so all of that is relevant.

18 While it may not be something that was actually
19 submitted to Medicare or to a federal payer, it's still
20 relevant when discussing *Thayer* in this larger idea of
21 what's the scheme and what's the reliable indicia under
22 *Thayer*.

23 And so the other two cases here, there's some
24 really, really good language about -- at least in one case
25 in the external peer review, it's a four-level fusion from

1 2012. And that was -- and in that instance Life Spine
2 product was used. And in the previous case there was
3 bullet cages used. And in the next case Life Spine
4 products were used. And that's in the complaint in
5 paragraphs 275 and 281. In there the reviewer found
6 that the additional two --

7 THE COURT: Ma'am, whoa. Whoa. Two different
8 cases, and I don't know what you're looking at. What are
9 you talking about?

10 MS. ROCHE: I'm sorry. So we're talking about
11 the four representative cases that the defendants have
12 been discussing this their chart At the end of their
13 complaint. There's three external peer review patients,
14 essentially, that are discussed in the complaint. So the
15 first one that I'm talking about is discussed in the
16 complaint at paragraphs 275 and 281.

17 And it's really just to say to the Court that
18 the reviewer there found that Dr. Asfora was aggressive,
19 and that going additionally above two levels and adding
20 two levels in a spinal surgery went against conventional
21 neurosurgical teaching and practice.

22 But essentially at this point, I've been talking
23 for a long time about it, but I think the important thing
24 to note here is just that most of the -- the four example
25 cases that we have, one that was an internal peer review

1 and three that were external peer reviews, are relevant to
2 the analysis under *Thayer*. The 20 surgeries that were
3 discussed in the complaint, and also that the defendants
4 put on their example here in the slides, are all relevant
5 and should be considered as far as what was motivating
6 Dr. Asfora to do a lot of these surgeries.

7 And so I think *Thayer* tells us that the
8 government's detailed recitations of the schemes involved
9 here, with extensive allegations and extensive details
10 about the scheme, and the reliable indicia that we just
11 talked about and that Polukoff discussed are sufficient on
12 their own to satisfy Rule 9(b) in this instance.

13 But as is sort have been alluded to here in the
14 alternative, the government does have a representative
15 example case. It is the case whose patient's name we will
16 not say. But --

17 THE COURT: What paragraph are you looking at
18 now?

19 MS. ROCHE: Yes, sir. Absolutely. So first we
20 would be looking at in the complaint, this patient would
21 be discussed at paragraph 282. And paragraph 282 notes
22 that this patient was a Medicare beneficiary and has the
23 date of birth year as 1942.

24 And then there's a discussion about in 287 and
25 288 of the complaint about the ways that a reviewer found

1 that the procedure discussed was aggressive, more
2 specifically in the language that was actually used that
3 this was a four-level fusion. And the reviewer noted that
4 these are rare surgeries performed in a patient without
5 spinal cord compression. The reviewer also noted here in
6 287 that the patient's complaints of mostly neck and arm
7 pain could have been addressed with fewer levels included
8 in the surgery. In 288 the reviewer also alleged that
9 Asfora did not document in any of the paperwork associated
10 with surgery or post-op care why he had extended the
11 fusion into the upper thoracic spine. And the reviewer
12 noted that they can be dangerous and rarely are performed,
13 particularly in the case of the patient here.

14 And again, this is where the reviewer said that
15 this case would be subject to peer review --

16 THE COURT: Excuse me. Let me ask a question.
17 With regard to 288, you know, it says it would be -- such
18 fusions can be dangerous and normally aren't performed
19 particularly in degenerative spine cases like patient
20 blank. In conclusion, the reviewer warned that in an
21 academic medical center with peer review and other spine
22 surgeons, such a case would quality for a morbidity and
23 morality discussion.

24 What does that mean, a morbidity and morality
25 discussion? I think that's code for -- what?

1 MS. ROCHE: I can't say that I know. I would
2 just assume that it would be sort of round-tabled on what
3 was done wrong, what was done right, correct or incorrect.
4 But that's just me speculating at this time on that.

5 But I think the important part of that paragraph
6 is that what was done was dangerous and rarely are
7 performed, especially in this instance, talking about
8 potential patient harm and also talking about going above
9 and beyond what was necessary and reasonable for this
10 patient based on this patient's symptoms and history and
11 whatever the case may be.

12 And then importantly, as well, in the next
13 paragraph, which is 289, the government alleges that then,
14 thereafter, Sanford submitted those claims to Medicare for
15 payment. And it was the amounts that were paid for the
16 claim.

17 And also relevant is paragraph 38 of the
18 government's complaint where the government alleges that
19 for all of the complaint discussed in the complaint,
20 meaning the specific patients, Dr. Asfora was certified to
21 CMS that what we've done was reasonably and medically
22 necessary.

23 THE COURT: Let me go back to 277, make sure you
24 covered that. 277 where it say reported that the patient
25 presented with no signs or symptoms of neurologic

1 dysfunction and had a normal EMG with no evidence of
2 myopathy. To me, to the lay person, that means there
3 wasn't a reason to operate on them. Am I misreading that?

4 MS. ROCHE: Are you in 287? Or 277?

5 THE COURT: 277.

6 MS. ROCHE: Oh, just one moment. Yes, I would
7 agree with your lay interpretation of that, especially at
8 the pleadings stage, which we don't yet have an expert.
9 We will get an expert. Defendants will get an expert.
10 Discovery where everyone will go through all of these
11 medical records line by line and talk about what
12 indications were there for surgery, what the history was,
13 did they try any alternatives. Were there -- did they try
14 therapy, did they try shots, did they try this, did they
15 try that.

16 But I agree with Your Honor's assessment in this
17 instance. And I think at least in one instance these
18 reviewers would say things like, "if any procedure was
19 necessary at all," or something, some qualifying language
20 to that. And I would say that -- I would imagine that
21 reviewers in the peer review setting are more -- withhold
22 or use appropriate language more so than experts for both
23 defendants and for the government would use when analyzing
24 a case like this.

25 But yes, I agree with the Judge's assessment in

1 277.

2 All right. So as we just discussed in the
3 representative example of the patient who will not be
4 named, but at least in the information the Court is aware,
5 and there's also as was discussed, essentially the United
6 States has met its burden under 9(b); under either the
7 *Thayer* test that we just discussed or the records of the
8 example that was pleaded with particularity regarding that
9 it was excessive care of this patient's procedure, that it
10 was submitted to Medicare. It's also important that it
11 involved an implant in which Medical Designs distributed
12 the device and Dr. Asfora got monetary payment as a
13 result.

14 So the next --

15 THE COURT: Let me ask you, let me ask you --

16 THE DEFENDANT: Yes, Your Honor.

17 THE COURT: If you -- hypothetically, if you
18 haven't shown enough under 9(b) for pleading medical
19 necessity, just hypothetically assume that, then why, in
20 your lawsuit?

21 MS. ROCHE: Well, in theory what the kickback
22 violation -- because we've claimed two varieties of
23 falsity under the False Claims Act. And so the first
24 version of the falsity, the ownership -- you know, the
25 ownership theory or basically the violation of the

1 Anti-Kickback Statute remains. So that would be the stage
2 unless there's an amended complaint in the future.

3 THE COURT: All right. Go ahead.

4 MS. ROCHE: All right. The next argument that
5 defendants raise is sort of a blurring, talking about an
6 objective standard or the need for sort of more of a
7 bright line standard on what sort of -- and a type, I
8 guess, of procedure. It's really talking about the degree
9 sort of incident, again.

10 But I think this really goes to a broader sort
11 of interpretation of objective falsity or whether or not
12 medical necessity claims can be false, because medical
13 judgments cannot be false. Which that theory should be
14 rejected. That is not the clear law. The clear law is
15 medical opinion can be false and are not shielded from
16 scrutiny under the False Claims Act. And that's the
17 *Polukoff* case.

18 And we're going back and forth talking about
19 medical necessity claims and who's arguing which cases
20 they didn't control. And this party is arguing that other
21 cases control. But at the end of the day, all the parties
22 can see that there are instances of medical necessity
23 claims -- that in fact have survived the pleading stage of
24 litigation, and have proceeded to discovery, have
25 proceeded to trial, and have gotten past this point.

1 As far as I know, nothing in the case law
2 suggests that there has to be this objective standard or
3 that it has to be so clear-cut. I think the more helpful
4 analysis when talking about what should be considered as
5 far as medical judgment is really that medical opinions
6 may trigger liability for fraud when they're not honestly
7 held by their maker. And that's from the *Paulus* case,
8 P-A-U-L-U-S, cited in our brief. Or when the speaker
9 knows of facts that are fundamentally incompatible with
10 his opinion. And that's, again, a Sixth Circuit case
11 talking about medical judgment and opinions and when and
12 how those should be sort of parsed.

13 And I guess it's really -- what we're saying
14 sort of at this stage is really -- this isn't an
15 appropriate determination to be making at the pleading
16 stage, talking about who did what and who views what
17 as being correct or incorrect or was standard for spinal
18 surgery is the standard. And that's just really not what
19 the law says or what we're required to do at the pleading
20 stage. It clearly does much more.

21 If we get into discovery and are able to depose
22 Dr. Asfora about specific surgeries and what was in his
23 mind, what was not in his mind, and I think the *Paulus*
24 case where it says opinions may trigger liability for
25 fraud when they are not honestly held by their maker.

1 Considering the fact that Dr. Asfora has this financial
2 incentive in the back of his mind for every procedure that
3 he's doing, it can lead to the conclusion or the inference
4 at this stage, based on the facts alleged in all the
5 schemes, that his belief may not have been honestly held
6 that all of the levels were necessary for the patients
7 discussed in the complaint. But that's an issue for
8 discovery. That's an issue for once the experts are
9 involved and the medical records are discussed.

10 THE COURT: Just --

11 MS. ROCHE: I would also like to note --

12 THE COURT: I have a question. I have a
13 question.

14 What about if Dr. Asfora with the same setup
15 that he has with actually two corporations, what about if
16 he would have not profited, but simply had office overhead
17 for the two women that he had working in the office and
18 the rent for the -- well, there were two offices, one
19 right next to each other, I guess. And let's say that he
20 didn't make a dime out of it and he was just -- you know,
21 for whatever reason wanted to see his patented products
22 all involved and in his patients.

23 If that were the case, would we have a violation
24 under any theory?

25 MS. ROCHE: I don't know if I want to make a

1 bright line assertion on that step. But I do think that
2 was -- that's the alternative for innovation. And that
3 was the advice that he was given at the time of the Aegis
4 agreement, essentially. You can do it if you want to, but
5 make no profit, or don't make any money off of this
6 because then you're not incentivized by your own surgical
7 procedures.

8 So I think, you know, not locking in the
9 government with that specific fact of Aegis, with the
10 markup and -- again, depending on the facts. Because in
11 the instance of Aegis, there were two other distributors
12 in the Sioux Falls area that easily could have sold that
13 product outside of Medical Designs. And Dr. Asfora and
14 Medical Designs aren't involved in that transaction at
15 all, and so there's no concern whatsoever rather than
16 being smack dab in the middle of it.

17 But I would say for the most part that's
18 definitely better; that's definitely closer to the true
19 purpose of innovation and trying to make the medical field
20 better. But it's not to say that physicians can't profit;
21 it just has to be done more in line with the situation
22 like the Orthofix agreement where there's royalties, and
23 the physician continues to use that product in his or her
24 practice as they normally would, understanding that
25 they're not profiting off of it. Any royalties that that

1 surgeon makes from that legitimate innovation that's used
2 by other people across the United States and maybe the
3 world is that they make money off of the broad usage
4 across the United States, and they don't make any money on
5 their own use of the product. This is exactly what's at
6 issue here.

7 And so I think it's hard to sort of step through
8 a lot of those issues. But Aegis is a little bit
9 difficult because, like I said, there was two other
10 representatives that are discussed in the complaint, Pete
11 Sanchez and Jesse Talcott, that were capable of
12 distributing Aegis products without Medical Designs being
13 in the middle.

14 And the bullet cages is different. The bullet
15 cage is different because there's not really any other
16 users of that product whatsoever, across the United
17 States; which I think that's more appropriate for a trial
18 argument or for discovery. But we do allege that it was
19 essentially just Dr. Asfora after a certain time period
20 that was utilizing the bullet cage.

21 And so the "take no profit" is much better, Your
22 Honor, but just with those items that I noted as far as
23 there was already distributors for Aegis, and that
24 Dr. Asfora knows how to innovate and knows how to sell an
25 invention to another company for the company to

1 distribute. And then he can still utilize the product and
2 does not make a profit off of it.

3 THE COURT: Let me ask you another hypothetical.
4 Let's assume, once again, that Dr. Asfora isn't making
5 anything himself, it's just meeting the overhead on the
6 selling of these devices, whichever device we're talking
7 about. But let's assume further, though, that Dr. Asfora
8 likes to operate, and he wouldn't normally make any money
9 off of inserting any of his devices; nonetheless, he
10 engaged in medically unnecessary surgery, for which he
11 would have been paid his surgical fee but nothing more
12 than that. Then would that then be a violation of --
13 under either of your theories?

14 MS. ROCHE: Yes. That would be a violation of
15 the medical necessity theory. We wouldn't necessarily be
16 able to establish that the claim was tainted by kickbacks,
17 which is the first falsity argument. But the medical
18 necessity concerns about being overly aggressive, billing
19 Medicare as a result, providing more procedures or more
20 extensive procedures than the patients need demanded, and
21 we had similar sort of the indicia that we've talked about
22 here. Maybe there's complaints, maybe there's -- maybe
23 there is a standard that he's violating in spinal surgery
24 as a result. But yes, I think that a plausible medical
25 necessity claim, more likely than not, not a kickback

1 degree claim.

2 THE COURT: All right. You can go ahead.

3 MS. ROCHE: Furthermore, Your Honor, we're also
4 talking about sort of a medical judgment question. And
5 really I think that the *Palin* case, P-A-L-I-N, we cited in
6 our brief is also relevant to the facts here, knowing that
7 Dr. Asfora is profiting personally off of surgeries. In
8 *Palin*, there a reasonable jury could find that defendant
9 ordered the tests that were relevant in that case to
10 generate income for themselves. I think based on all of
11 the evidence that we've alleged in the complaints as far
12 as generating income, interests in devices, and the amount
13 of devices that Dr. Asfora implanted in patients, that the
14 same result could be true; that a jury here could also
15 find that the reason in part, in whole or in part, that
16 Dr. Asfora performs at least the example case and any
17 other cases that are found to be medically unnecessary in
18 the discovery process, the jury could find that he
19 performed maybe an entire surgery or more extensive
20 surgeries than necessary; based on the fact that he was --
21 in whole or in part that he was making money off of those
22 surgeries. So we think that *Palin* is also relevant there.

23 All right. The next allegation is talking about
24 Dr. Asfora's knowledge about what he knew regarding
25 whether or not certain of these claims alleged in the

1 complaint were medically unnecessary. Again, what
2 Dr. Asfora knew will be determined more extensively after
3 the pleading stage in discovery. But at this point -- at
4 this point in the -- the *Reliance* case, which I think is
5 helpful for the fact pattern here of where we are, the
6 *Reliance* case is the Central District of California
7 pleading, a case from 2014, cited in our brief. In there
8 the Court found that if the United States is successful in
9 proving that the physician investors received unlawful
10 kickbacks for their use of certain devices, it is
11 plausible to infer that defendants, those that offered the
12 kickbacks or were the distributor of the device, knew that
13 the physicians would do whatever it took to continue
14 receiving such large kickbacks, including performing
15 unnecessary or more extensive than necessary surgeries.

16 And so I think that *Reliance* could apply not
17 just to Dr. Asfora, but could apply to Medical Designs and
18 could apply to Sicage for the assumption that if kickbacks
19 were involved, and I think if we've sufficiently pleaded
20 at this stage, but further on if we prove that Dr. Asfora
21 was receiving kickbacks from Medical Designs and some from
22 Sicage, then it also leads to the inference that those
23 folks would know that the doctor would do whatever it took
24 to continue making money.

25 And also Dr. Asfora, you know, he -- it's all of

1 the things that we discussed earlier about all of the
2 different learnings and all of the different things that
3 folks have said that he, himself, was privy to as far as
4 multi-level surgeries being too aggressive, his spinal
5 surgeries being too extensive. I don't know any of those
6 things standing alone is enough; but all of those things
7 together, all of nine various warnings, the peer review
8 processes, Dr. Asfora received all of the final findings
9 of the internal peer review processes. That's alleged in
10 the complaint. He saw the external peer reviews and has
11 had access to the external peer reviews prior to this
12 lawsuit.

13 So considering that the knowledge of what his
14 partners thought and the relaters thought and the folks --
15 the physicians that complained about Dr. Asfora's practice
16 and how it had changed, coupled with their viewing of the
17 internal peer review, the external peer review, I think
18 that leads to a plausible conclusion that Dr. Asfora knew
19 that he was performing unnecessary medical procedures.
20 And certainly, again, if you consider the kickback, that
21 allegation being thrown in the mix, and looking at the
22 *Reliance* case and understanding the plausible inferences
23 from a kickback and leading to medically unnecessary
24 procedures, I think we've satisfied that final element or
25 that final argument that defendant's discussed on

1 Dr. Asfora's knowledge on medically unnecessary claims.

2 I just want to be sure, do any of my colleagues,
3 did I leave anything out on the medical necessity piece or
4 does the Court have further questions on the medical
5 necessity piece?

6 THE COURT: No. I don't have any further
7 questions. Thank you.

8 Does the defense have any rebuttal it wishes to
9 make?

10 I've read a fair number of -- not all, but a
11 fair number of the cases that were cited, but I'm not on a
12 first-name name basis. And as you were going through,
13 sometimes you would say this case or that case, you know,
14 without citation, and only one name. Well, I'm not that
15 familiar with the cases generally. So I would ask that
16 you -- even though they're cited in your brief, with
17 regard to the cases that you specifically referred to in
18 your argument, send me a letter with a copy to the
19 defendant that such was the case name in full and the
20 citation to the case.

21 MS. ROCHE: Yes, Your Honor.

22 THE COURT: All right. Let me hear from the
23 defense.

24 MR. GEYERMAN: Thank you, Your Honor. There's a
25 lot there. But let me try to step back and map it out for

1 you as to how we see the claims are asserted and the
2 doctrine fitting into the six dismissal arguments that
3 we've asserted.

4 Early on in the presentation the government
5 referred to there's many schemes, they're all swirling all
6 around, it was this sort of big mass of different theories
7 of a lot of different thing that were done wrong. But I
8 think ultimately, and frankly in response to Your Honor's
9 very good question, it became evident that they have two
10 separate and distinct theories of liability. Because when
11 you said if I dismiss the medical necessity theory, what's
12 left? And they said, I have my ownership kickback theory.

13 They are asserting that there is an ownership
14 kickback violation, and therefore a False Claims Act
15 violation, whether or not there was any medically
16 unnecessary surgeries performed. Analytically these are
17 two separate and distinct theories.

18 So, on the ownership kickback theory -- and not
19 to step on my colleague Mr. Graham's toes, but I think --
20 there's a couple of real big picture points that frankly
21 the government can't contest, and we would submit are
22 really the underlying point of our dismissal argument.

23 Number one: The government has never said that
24 it is a violation of the Anti-Kickback Statute to own a
25 medical device company, use that company's devices in your

1 surgeries, and three, take a profit distribution because
2 you are an owner. That -- those are the three basic
3 elements of their ownership kickback theory here. And
4 yet, there is not a single case guidance from the
5 Department of Health and Human Services or the Department
6 of Justice that has ever said when those three conditions
7 are satisfied, you have an Anti-Kickback Statute
8 violation. Point one.

9 Point two: Dr. Asfora lived through the DuBay
10 investigation. And coming out of that investigation it
11 was known he owned Medical Designs, that he used products
12 that Medical Designs manufactured in his surgeries, and
13 that he took a profit distribution because he owned the
14 company.

15 Those are the three basic facts that the
16 government says are sufficient for them to make out a
17 violation under their ownership kickback theory; and yet,
18 they're the very facts that have never been found to be
19 sufficient to state a claim, and they're the very facts
20 that nobody ever told Dr. Asfora after the DuBay
21 investigation created a problem.

22 So where there's all of these allegations in the
23 complaint about this person told Dr. Asfora this might be
24 risky, or this person told Dr. Asfora don't do that, at
25 the end of the day, all they're suing him on under the

1 ownership kickback theory is owning a device company,
2 using that device company's products, and taking a profit
3 for distribution. Nothing else. Nothing else matters.
4 And there's no well-put allegation in the complaint that
5 would show that Dr. Asfora thought coming out of the DuBay
6 investigation that it was inappropriate in any way for him
7 to keep using product from his own company.

8 So those are big picture points on the ownership
9 kickback theory; and nothing that the government said to
10 you in that long presentation undermines any of those
11 points, I would submit.

12 Now let's pick for the moment to the medical
13 necessity theory.

14 THE COURT: You're putting -- wait a minute.

15 Let's talk about the DuBay case and the spin
16 that you put on it, which in all -- I'm looking at the
17 judgment on the pleadings. And I'm looking at a summary
18 judgment motion. And I think it would be fair to say from
19 my point of view that you're putting absolutely the best
20 spin on the DuBay settlement possible. And I don't think
21 that I look -- I should look at it in that manner.

22 Because it seems to me it actually required
23 quite a bit of chutzpa to say that he comes out of that
24 and he thinks that what he's doing is okay. I think the
25 contrary is probably true.

1 But in any event, I can't see that on a motion
2 for directed verdict -- or excuse me -- a judgment for
3 judgment on the pleadings, that I should adopt your
4 reading of DuBay.

5 MR. GEYERMAN: I would respond this way, Your
6 Honor. Number one, the statute that's allegedly violated,
7 the Anti-Kickback Statute, which requires a knowing and
8 willful violation of the law -- so it's an even higher
9 mens rea standard than it is a violation of the False
10 Claims Act itself, which is a mere knowing violation of
11 the law.

12 So number one, it's about the highest mens rea
13 standard that you can get --

14 THE COURT: Just a second. Wait a minute. Wait
15 a minute.

16 It seems to me that we're talking about a jury
17 question. The claim is in the -- among other things in
18 the complaint -- that he said now let's be quiet about
19 this, let's do this undercover, and so on. That's what
20 they're claiming. And that sounds to me like a jury
21 question as to what is this fellow 's -- Dr. Asfora's
22 state of mind when he tells this to people? He can say
23 well, I didn't want the hospital people to think I'm
24 making a lot of money, or whatever. We can have his
25 explanation.

1 But we're talking about a fact question here
2 with regard to somebody's state of mind, with regard to
3 his scienter, and that isn't something that can be
4 appropriate or that can be determined in a motion for
5 judgment on the pleadings.

6 MR. GEYERMAN: Your Honor, we're simply asking
7 you as the reader of this complaint, you believe they've
8 asserted a plausible basis for all prima facie elements of
9 the point. And where one of those prima facie elements is
10 a knowing and willful violation of the Anti-Kickback
11 Statute. And where it is an undisputed allegation that he
12 lived through the DuBay investigation, and it's also
13 undisputed that DuBay did not say it is impermissible to
14 be an owner of Medical Designs and keep using your bullet
15 cage, which is a product the patent of which is owned by
16 Medical Designs, there's no allegation we submit anywhere
17 that a reasonable person would infer from it, jeez,
18 Dr. Asfora thought it would not -- he couldn't use the
19 bullet cage and take profit distribution from Medical
20 Designs. We just don't think that's in there.

21 Now, if you want to parse out some allegations
22 about different products, you know, they did at one point
23 in their complaint say there's six different schemes here,
24 and they defined the schemes by different products -- you
25 know, bullet cage is one, Life Spine product is another --

1 each of those different products might have a little bit
2 different story that comes with it.

3 But the biggest one and the lead one they start
4 with is the bullet cage, which was the entire focus of the
5 DuBay investigation. And Medical Designs manufactures it,
6 he uses it in his surgeries, and because of that in part
7 Medical Designs takes a profit. Nobody told him that was
8 inappropriate, and there is no allegation in the complaint
9 that he ever thought that it was.

10 THE COURT: Wait a minute. Nobody tells him
11 it's inappropriate? His own lawyer did, apparently.

12 MR. GEYERMAN: That allegation applies to only
13 one of the two license agreements that happened years
14 later. It doesn't have any application to deal with, I
15 believe, five out of the six products in the complaint.

16 So the government wants to have its cake and eat
17 it too here. In many respects they are saying there's
18 multiple schemes because there's multiple products, and
19 they're cherry-picking facts from one business deal and
20 trying to imply that that suggests a belief in someone's
21 mind that there is a kickback problem as to all six
22 products.

23 If Your Honor thinks that that is a relevant
24 fact for purposes of evaluating the plausibility of the
25 claim, then we would submit the allegation goes no further

1 than its need; which as to the one license arrangement
2 that that legal advice came in the context of. It has
3 nothing to do with the other five products or five
4 (indiscernible). That's my only point.

5 I think it has become apparent that analytically
6 ownership kickback theory is to stand independent of a
7 medical necessity theory, as Your Honor's really pointing
8 question, and good questions, fleshed out for the
9 government.

10 So now we'll talk for a moment about the medical
11 necessity theory. First is the government spent a lot of
12 time the proposition that under Eighth Circuit precedent
13 they have to prove a representative example. The
14 government reads *Thayer* as standing for the proposition
15 that they don't have to. We actually believe that *Joshi*
16 and both *Thayer* cases stand for the proposition that they
17 do. If Your Honor thinks that that is a material dispute
18 of law point, we would be happy to submit some additional
19 briefing on that issue, if Your Honor would like. If the
20 respective sample rule applies, we win.

21 They haven't alleged more than one patient here.
22 And the rule is some repetitive examples, plural, not one
23 example. And that one patient that they have where they
24 critique the quality of the surgery, and is the federal
25 issue, that's all thief got.

1 Your Honor asked a good question about how come
2 in the prior complaints in this case there was a lot more
3 information and search about unnecessary surgeries that
4 for some unknown reason don't make it into this complaint.
5 I'll draw my inferences, as others will about that, but
6 we're left with one surgery for a federal beneficiary
7 where they are making some critique on the quality of
8 care.

9 Even if, however, Your Honor disagrees with us
10 that they don't have to prove representative samples of a
11 surgery that was medically unnecessary, we still have two
12 different grounds on which you can dismiss the entire
13 medical necessity claim.

14 Number one is that the nature of the allegations
15 don't rise to the level of asserting a plausible medically
16 unnecessary procedure. And we have on our slides, at
17 least, put forward the full pleading on slide six of what
18 we would say are, frankly, the four best cases --

19 THE COURT: Just a minute. Just a minute. Let
20 me ask you specifically with regard to paragraph 277 in
21 the complaint, where board certified neurological surgeon
22 says that the patient presented no signs or symptoms of
23 neurologic dysfunction, had a normal EMG with no evidence
24 of myopathy, that indicates to me there wasn't any reason
25 to operate on him.

1 MR. GEYERMAN: Well, Your Honor, that's not what
2 the -- that's not the language that they used. And I'm
3 not a doctor, so -- but the government didn't really know
4 how to answer that question. And I submit we shouldn't be
5 guessing about what that means from a medical perspective.

6 If you look at paragraph --

7 THE COURT: That wasn't the paragraph where I
8 was at. I asked about -- but then I asked about another
9 one was -- just a minute.

10 MR. GEYERMAN: I know. Actually, before you
11 move off of 277 --

12 THE COURT: 277, I don't believe, is what I
13 asked a question about. I asked a question about 288
14 was -- the review in an academic medical center peer
15 review from other spinal surgeons, such a case would
16 qualify for a morbidity and morality discussion.

17 That sound ominous to me, but I don't know in
18 medical code what exactly that means. It sounds like
19 morality? Morbidity? That's death.

20 MR. GEYERMAN: They certainly cast it with the
21 intent that the reader is going to imply that it's
22 something ominous. But that's my point, is to if they had
23 attached the entire report that was provided by this
24 reviewer, it would give the Court on a Rule (9) (d)
25 analysis a chance to look at a much more bigger picture

1 and see it in context, what is this actually saying?

2 Now, I wanted to address 277 and 278 in
3 particular, because that was another one of the paragraphs
4 that you asked counsel what does this language mean? And
5 then your reading of the last sentence of 277 was like
6 there's nothing wrong with this patient, so why would you
7 operate at all on them? If you look at the very next
8 paragraph, 278, the thrust of the further commentary on
9 that surgery seems to be -- it was appropriate to operate
10 on vertebra C5-C6 and the C6 and 7 levels, but adding two
11 more levels on top of that is what the reviewer took issue
12 with.

13 So 278 may seem in conflict with 277, which may
14 say this person had nothing wrong at all and therefore no
15 surgery at all should have been performed on them. The
16 allegations are in conflict with one another insofar as
17 278 suggests there was some amount of the surgery that was
18 okay and it ended up what was done was just too much.

19 And as to 288, I would point you to the
20 paragraph 287 immediately above that, which is about the
21 same patient. And it's -- and there the comment is that
22 the surgery that was performed is a rare surgery. It's
23 not saying it's unprecedented. It's not saying no
24 reasonable surgeon would have performed it.

25 And the last sentence of 287 is saying that the

1 doctor -- or that this reviewer thought that the symptoms
2 could have been addressed with fewer levels.

3 Now, are we quibbling about what this means? We
4 are. However, the standard for asserting plausity of lack
5 of medical necessity is very high. It's not enough to say
6 different surgeons would come to differing conclusions.
7 That's just sort of your traditional debate about experts.

8 Medical -- lack of medical necessity means there
9 was no medical justification, period; no reasonable
10 surgeon could make the medical decision that this surgeon
11 did. And we have cited four cases at the motion to
12 dismiss stage (indiscernible) the nature of the
13 allegations did not rise to the level of saying there was
14 no medical justification at all.

15 And we would be happy in a nice pithy letter to
16 send those citations to you, because they're obviously
17 intermixed with our much longer brief, after this
18 argument.

19 But I think we need to keep in mind just how
20 difficult it is to assert plausibly a claim for lack of
21 medical necessity. If you are using a surgery for a
22 purpose that the medical community universally says it
23 should not be used for, it could have said (indiscernible)
24 this: If you are using a surgery that is shown to have no
25 medical value at all, cases have said that's enough to

1 reach a motion to dismiss. But we have yet to see a case
2 where allegations that are about this incremental of a
3 disagreement, how many different levels of a spine fusion
4 is too many, that is the proper basis.

5 The last two things I'll make, and then I will
6 stand down.

7 There's two cases that the government's talked
8 about. One was the *Palin* case, and they cited it in her
9 argument for the proposition that it shows that -- how
10 much this is a jury question. Respectfully, we think that
11 the more appropriate cases to look at are motions to
12 dismiss cases. Because those are the cases that are
13 applying the standard that Your Honor has to apply right
14 now, which is what allegations in a complaint meet a
15 plausibility standard.

16 Once this case gets past the motion to dismiss
17 stage and past the summary judgment stage, then when the
18 jury returns a verdict, to overturn that verdict is going
19 to be a no-reasonable-juror-could-find standard. And
20 that's what *Palin* was applying, which is not the same
21 standard that a court on a Rule 12 and 9(b) motion is
22 considering. So I don't think *Palin* is the right standard
23 to look at, because it's really in a different procedure
24 posture, and therefore it's confusing.

25 Finally, as to the *Reliance* case out of the

1 Central District of California, the *Reliance* defendants
2 did not include the defendant surgeon. And in that case
3 the defendants were investors in a medical device company
4 who are asserting that there were no plausible allegations
5 of scienter. They were not making the additional argument
6 that Dr. Asfora is making in this case, which is the
7 allegations were insufficient to suggest that the surgery
8 was unnecessary in the first place.

9 So we submit, quite frankly, this issue was
10 given pretty short-shrift in the *Reliance* case. We felt
11 very clearly as to making one argument as to the
12 sufficiency of a lack of necessity allegations, which goes
13 to falsity. And separate and apart from that, we're
14 making allegations about the sufficiency of his supposed
15 scienter, which is a separate and independent ground that
16 a case could be dismissed on -- at the motion to dismiss
17 phase.

18 And with that, I will stand down unless my
19 colleague Mr. Graham has anything more to add. I
20 appreciate your time.

21 MR. GRAHAM: Nothing at all. Thank you, Grant.

22 THE COURT: All right.

23 MS. ROCHE: Your Honor, can I just ask a quick
24 question? I don't mind to interrupt you while you're
25 thinking.

1 THE COURT: Beg pardon?

2 MS. ROCHE: I don't mean to interrupt you while
3 you're thinking. Is it okay if I just ask one clarifying
4 question?

5 THE COURT: Clarifying question of who?

6 MS. ROCHE: Of you. I was just going to say, we
7 responded on medical necessity and got into the
8 Anti-Kickback Statute violation somewhat in the middle of
9 that. But if there's any other questions the Court has
10 for us on DuBay or about anything else that was raised
11 more close to the ownership theory that I haven't had a
12 chance to respond to, I'm happy to answer those questions.
13 But I also know we've been sitting here a long time and
14 the Court has very thoroughly reviewed everything and
15 asked great questions. But I just didn't want you to
16 think that we've waived any of those arguments by --

17 THE COURT: I have no illusion that you've waved
18 anything, I'll tell you that.

19 MS. ROCHE: But otherwise I'll be quiet unless
20 you think of something you want me to answer for you.

21 THE COURT: No.

22 Well, the case is going -- I'm going to look a
23 little more at the medical necessity pleading, because I
24 think it's thin. Whether it's nothing -- I know, I spent
25 plenty of time on this thing. But I wanted to hear

1 argument to see if it would help me.

2 And, you know, it's a 9(b) pleading. And I have
3 to look to see if, you know, as the government in essence,
4 it seems to me, urges that cumulatively is enough. And I
5 want to, frankly, re-review things in light of argument on
6 medical necessity.

7 On the kickback theory, the motion is denied.
8 The cause of action stated that the only thing that I'm
9 looking at -- and that's true, denied too, is the other
10 alternate theories that were pled.

11 But on the medical necessity theory, I want to
12 consider that further. I'll rule subsequently on the
13 medical necessity theory.

14 Now, we have everybody together so I wanted to
15 talk to you a bit about -- assuming just for purposes of
16 discussion that this case survives summary judgment, then,
17 you know, in scheduling I'm going to have to set time
18 aside for the trial, assuming it gets to trial. So I
19 realize it's very, very preliminary to be asking anybody
20 anything, because we don't even have an answer yet. And I
21 haven't ruled yet on the medical necessity theory.

22 But if that claim ultimately goes ahead, that
23 would involve some evidence that won't be otherwise in the
24 case, I think. But recognizing those limitations, while
25 talking about it just generally, I wanted to know how long

1 the parties thought trying this case would last.

2 Some of you are familiar with me in trial; some
3 of you aren't. I start at 9:00 in the morning and go to
4 noon, starting usually at 1:00 and going until 5:00. And
5 I don't set any time restraints upon anybody. The
6 lawyers, if they're going to bore the jury, that's their
7 risk.

8 And I have counsel approach the bench if there's
9 something that -- for instance you think something should
10 be coming into evidence and it isn't. I keep on
11 sustaining an objection. I'll allow counsel to approach
12 the bench, and I'll tell you what your problem is. You
13 might be able to solve the problem, or it might be a dead
14 duck on the issue. But at least we have them without
15 having to send the jury out, and so on. But that doesn't
16 mean I want people traipsing up to the bench all the time.
17 But in order to facilitate evidence coming in, I'll do
18 that.

19 And with regard to the jury, unless the COVID-19
20 pandemic is gone or substantially gone by the time we try
21 this, instead of using a 12-person jury, which I would
22 prefer, I would use an eight-person jury. I don't prefer
23 those, because I think it's easier to get an unusual
24 result. I think the 12-person has a leveling effect.

25 But we can't try -- well, we could try -- we can

1 try with as few as six, civilly. But I want to have
2 alternates in case that we need them. So the eight will
3 decide if they're there at the end of the case, of course.
4 But if we lose one or two during the case, six can still
5 decide the case.

6 So I know this is very preliminary, but I have
7 to look at, at some point, in setting some time aside for
8 this. So how long does the government think this case
9 would last?

10 MS. ROCHE: It's hard to know, Judge, when we
11 don't know if medical necessity -- like you said, we don't
12 know if medical necessity would be included with all the
13 experts that would be involved and medical records that
14 would be shared back and forth. But I would say at least
15 weeks, based on all the evidence? A couple weeks?

16 THE COURT: Are you talking about your side of
17 it, or the whole works?

18 MS. ROCHE: Um, again, it's dependent on if
19 there's experts --

20 THE COURT: Right.

21 MS. ROCHE: -- for the necessity of a piece.
22 Probably the whole thing, I would imagine, could be done
23 in a month? But I would defer to others and my DOJ
24 colleagues, if they have opinions.

25 THE COURT: Um-hum. And then this is all super

1 preliminary, but I'm just trying to get a feeling for what
2 the -- what others think. What does the defense think?

3 MR. GEYERMAN: Your Honor, we haven't consulted
4 on that issue, so I don't think we're even really in a
5 position to say something meaningful. But these cases
6 generally are certainly multiple weeks.

7 THE COURT: That's a pretty safe estimate.

8 Yeah, I think it would vary a lot, depending on
9 whether medical necessity goes ahead. And of course the
10 rest of it is that even if I toss the medical necessity,
11 the government's already alluded to the fact that they
12 would try and strengthen their pleading. That would
13 depend upon what they have to strengthen it with, of
14 course.

15 Well, I think that's all that we can do today.
16 Is there anything further from the government?

17 MS. ROCHE: Just to clarify, the only thing
18 you're looking for us as we walk away is the letter with
19 our authorities cited herein. Is that correct? Copying
20 the other side?

21 THE COURT: Yes.

22 MS. ROCHE: Nothing further. Thank you.

23 THE COURT: All right. Anything further from
24 the defense?

25 MR. GEYERMAN: No, Your Honor. Thank you for

1 your time today.

2 THE COURT: All right. Thank you. We're in
3 recess.

4 (End of proceedings this date.)

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2 COURT REPORTER'S CERTIFICATE3 UNITED STATES DISTRICT COURT)
4 DISTRICT OF SOUTH DAKOTA) SS
5 WESTERN DIVISION)6 I, Sheri L. Not Help Him, RPR, CRR, Official
7 Court Reporter in and for the United States District
8 Court, District of South Dakota,9 DO HEREBY CERTIFY that I acted as such Court
10 Reporter for the Motions Hearing of the within-entitled
11 action, and that the foregoing transcript, pages 1 to 98,
12 inclusive, is a true and complete transcript of my
13 stenographic notes taken for said Motions Hearing on July
14 23, 2020.15 All appearances of participants in this hearing
16 were remotely by videoconference or telephonic conference.17 Dated at Rapid City, South Dakota, this 16th day
18 of October, 2020.19 */s/ Sheri L. Not Help Him*20 SHERI L. NOT HELP HIM
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SHERI L. NOT HELP HIM, CRR, RPR

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